IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LISA MCKERNAN, Derivatively on Behalf of Trevena, Inc., Plaintiff, v. MAXINE GOWEN, DAVID SOERGEL, CARRIE L. BOURDOW, LEON O. MOULDER, JR., MICHAEL R. DOUGHERTY, JULIE H. MCHUGH, JAKE R. NUNN, ANNE M. PHILLIPS, BARBARA YANNI, ADAM M. KOPPEL, Defendants, and Trevena, Inc., a Delaware Corporation, Nominal Defendant.	Civil Action No. **VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS, BREACH OF FIDUCIARY DUTY, WASTE OF CORPORATE ASSETS, AND UNJUST ENRICHMENT** JURY DEMAND

Plaintiff Lisa McKernan ("Plaintiff"), by her attorneys, submits this Verified Shareholder Derivative Complaint for Violations of Federal Securities Laws, Breach of Fiduciary Duty, Waste of Corporate Assets, and Unjust Enrichment, derivatively for the benefit of Nominal Defendant Trevena, Inc. ("Trevena" or the "Company"). Plaintiff bases her allegations on personal knowledge and, as to all other matters outside her personal knowledge, upon information and belief based on the investigation of counsel, which includes without limitation: (i) review and analysis of public filings with the United States Securities and Exchange Commission (SEC); (ii) review and analysis of documents prepared by or for the Food and Drug Administration (FDA); (iii) review and analysis of filings in state and/or federal court, including pleadings in the related securities fraud class action, *Tomaszewski v. Trevena, Inc.*, C.A. 2:18-cv-

04378-CMR (E.D. Pa.) filed October 10, 2018 (the "Securities Class Action"); and (iv) review and analysis of press releases, news reports, analyst reports, industry reports, investor conference call transcripts, and other information available in the public domain.

I. INTRODUCTION

1. This is a shareholder derivative action brought on behalf of and for the benefit of Trevena that seeks to redress wrongdoing by the Company's board of directors (the "Board") and certain of its senior officers.

2. From at least May 2, 2016 and continuing through the present (the "Relevant Time Period"), the Individual Defendants[1] breached their fiduciary duties owed to Trevena and its shareholders and committed other violations of federal and state law by, *inter alia*, causing or allowing the Company to issue materially false and misleading statements and omit material information from its public filings and communications, the disclosure of which would have made such statements not misleading.

3. Trevena is a clinical-stage biopharmaceutical company. Throughout the Relevant Time Period, Trevena's leading drug candidate was oliceridine, also known as OLINVO or TRV-130, which the Company described as a "G protein-based ligand binding to the mu opioid receptor for the intravenous treatment of acute moderate-to-severe postoperative pain." The Company promoted oliceridine as a potential replacement for morphine.

4. On March 29, 2016, Trevena attended an End-of-Phase 2 trial meeting with the FDA about oliceridine, in order to discuss Trevena's proposed Phase 3 studies. At the meeting, the FDA staff privately advised Trevena that the FDA: (i) "did not agree with the proposed dosing in the Phase 3 studies"; (ii) "did not agree with the proposed primary endpoint"; and (iii)

[1] "Individual Defendants" means all defendants named in this Complaint except for Nominal Defendant Trevena.

"did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine."

5. Nevertheless, on May 2, 2016, the Company publicly announced that it had concluded a "Successful End-of-Phase 2 Meeting with FDA," where the Company "reached general agreement with the FDA on key elements of the Phase 3 program to support a New Drug Application (NDA) for oliceridine (TRV130)." Although Trevena's President and Chief Executive Officer (CEO) Maxine Gowen informed investors that Trevena was "very pleased with the outcome" of the meeting, she omitted to disclose the material fact that the FDA disagreed with Trevena's proposals regarding key measures of the Phase 3 study.

6. Despite knowing of the FDA's concerns and criticisms of Trevena's proposed Phase 3 studies, throughout the Relevant Time Period the Individual Defendants continued to misrepresent and/or allowed Trevena to misrepresent what transpired at the March 29, 2016 meeting and failed to disclose material facts necessary to make the statements that were made not misleading.

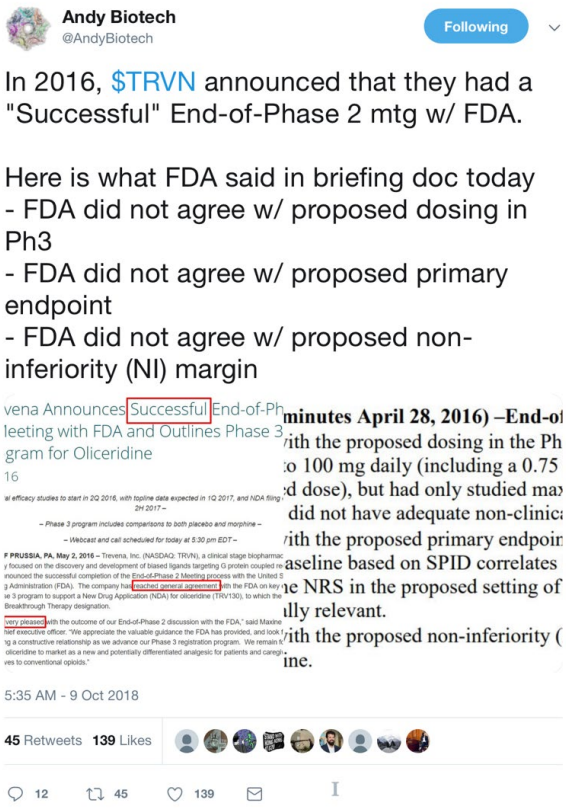
7. On November 7, 2017, Trevena issued a press release announcing that the Company had recently submitted a New Drug Application (NDA) for oliceridine, the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. As before, it failed to disclose the material fact that the FDA disagreed with key measures of Trevena's Phase 3 studies.

8. On October 9, 2018, in advance of the Anesthetic and Analgesic Drug Products Advisory Committee's October 11, 2018 meeting to discuss the NDA for oliceridine, during which the Advisory Committee would discuss the efficacy and safety data and benefit-risk considerations of oliceridine, the Advisory Committee released to the public an FDA Briefing

Document. The FDA Briefing Document presented details of the FDA's communications with the Company regarding oliceridine at the end of 2015 and beginning of 2016. The FDA Briefing Document contained information regarding undisclosed communications that Trevena had with the FDA, including that the FDA disagreed with key measures of Trevena's Phase 3 studies, which revealed for the first time the false and misleading nature of the information Trevena was disseminating to the public during the Relevant Time Period.

9. Investors and analysts were stunned by this development. Jefferies LLC Senior Equity Research Analyst Biren Amin responded by downgrading Trevena stock from Buy to Hold, while slashing his price target from $10 to just $1 per share. He commented, "A secondary objective of the studies was to demonstrate the superiority of oliceridine to morphine in terms of respiratory safety burden. To our surprise, [Trevena's] proposed endpoint for assessing respiratory safety burden was not supported by FDA, and this information was not disclosed to the public following the end-of-phase 2 FDA meeting."

10. Others quickly weighed in on the Company's blatant deception:



11. On this news, the price of Trevena stock fell $1.91 per share, or 64%, from the previous day's trading price, closing at $1.07 per share on October 9, 2018.

12. On October 11, 2018, the NASDAQ exchange temporarily halted trading of Trevena's common stock.

13. Also, on October 11, 2018, Trevena filed a current report on Form 8-K with the SEC providing information regarding the Company's past communications with the FDA concerning the design of the Phase 3 clinical trials for oliceridine. Later, that same day, the Company issued a press release announcing that the Advisory Committee "voted 8 against, and 7 in favor of, the approval of oliceridine for the management of moderate to severe acute pain in adult patients for whom an intravenous (IV) opioid is warranted." The press release moreover noted that the target date for completion of review by the FDA for the Company's NDA for oliceridine was November 2, 2018.

14. On November 2, 2018, the Company issued a press release disclosing that on that date Trevena received a Complete Response Letter from the FDA regarding the NDA for oliceridine, which stated that the FDA had completed its review of the NDA for oliceridine and determined that the data submitted was inadequate to support approval, and that the FDA would not approve oliceridine in its present form.

15. Thus, during the Relevant Time Period, the Individual Defendants breached their duty of loyalty and good faith by: (i) allowing the Company to press forward with its Phase 3 studies knowing that the FDA did not agree with Trevena's proposed dosing, its proposed primary endpoint, and its proposed noninferiority margin; (ii) allowing each other to cause, or by themselves causing, the Company to make improper statements in Trevena's press releases, public filings, and other public statements relating to oliceridine and the Company's key interactions with the FDA, including the March 29, 2016 End-of-Phase 2 meeting; and (iii) failing to properly maintain and/or adequately monitor internal controls which would have prevented the foregoing violations of law.

16. The Individual Defendants' violations of law have damaged Trevena in the form of, among other things, more than $150 million in losses to the Company's market capitalization, as well as significant harm to its reputation, goodwill, and standing in the business community. The wrongdoing has further exposed the Company to millions of dollars in potential liability from the Securities Class Action and the significant costs incurred and to be incurred in connection with the litigation and potential resolution of that action.

17. The Board will not commence litigation against the Individual Defendants named in this Complaint, let alone vigorously prosecute such claims, because its members face a substantial likelihood of liability to Trevena for authorizing or failing to correct the false and

misleading statements alleged herein, and for failing to implement and monitor the necessary policies, procedures, and internal controls to prevent the harm to the Company that has occurred. Accordingly, a pre-suit demand upon the Board is a useless and futile act. Thus, Plaintiff rightfully brings this action to vindicate the Company's rights against its wayward fiduciaries and hold them responsible for the damages they have caused to Trevena and its shareholders.

II. JURISDICTION AND VENUE

18. Pursuant to 28 U.S.C. § 1331 and section 27 of the Exchange Act (15 U.S.C. § 78aa), this Court has jurisdiction over the contribution claims asserted herein under § 21D of the Exchange Act, 15 U.S.C. § 78u-4(f). This Court has supplemental jurisdiction over the remaining claims under 28 U.S.C. § 1367.

19. This Court has personal jurisdiction over each defendant because each defendant is either a corporation conducting business and maintaining operations in this District or is an individual who is either present in this District for jurisdictional purposes or has, directly and indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mails, interstate telephone communications, and the facilities of the national securities exchanges and markets, such that each defendant has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

20. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391(b) because (i) Trevena maintains its principal place of business in this District; (ii) one or more of the defendants resides or maintains executive offices in this District; (iii) a substantial portion of the transactions and wrongs complained of herein occurred in this District; and (iv) the Individual Defendants have received substantial compensation in this District by doing business here and engaging in numerous activities in this District.

III. PARTIES

A. Plaintiff

21. Plaintiff Lisa McKernan is a current shareholder of Trevena and has continuously owned shares since January 2015.

B. Nominal Defendant

22. Nominal Defendant Trevena is a biopharmaceutical company focused on the development and commercialization of novel medicines. Trevena was founded in 2007 and is incorporated in Delaware and headquartered in Chesterbrook, Pennsylvania. The Company's common stock trades on the NASDAQ under the ticker symbol "TRVN." As of July 31, 2018, Trevena had 76,082,280 shares of common stock outstanding.

C. Individual Defendants

23. Defendant Maxine Gowen served as Trevena's President and CEO between November 2007 and October 2018, and has been a member of the Board since November 2007. Defendant Gowen co-founded Trevena in 2007. Gowen is named as a defendant in the related Securities Class Action that alleges she violated sections 10(b) and 20(a) of the Exchange Act. Defendant Gowen breached her fiduciary duties to the Company and its shareholders as described below. Defendant Gowen also knowingly, recklessly, or with gross negligence made (or allowed to be made) improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting. Between 2016 and 2018, Trevena paid Gowen as follows:

YEAR	SALARY	OPTION AWARDS	NONEQUITY INCENTIVE PLAN COMPENSATION	OTHER COMPENSATION	TOTAL COMPENSATION
2016	$513,917	$1,917,756	$260,000	$10,600	$2,702,273
2017	$536,667	$1,992,612	$268,785	$10,800	$2,808,864
2018	$431,650	$780,843	--	$944,435	$2,156,929

24. Defendant David Soergel was Trevena's Chief Medical Officer between March 2015 and August 2017, and Senior Vice President (SVP), Clinical Development between September 2012 and February 2015. Soergel is named as a defendant in the related Securities Class Action that alleges he violated sections 10(b) and 20(a) of the Exchange Act. Defendant Soergel breached his fiduciary duties to the Company and its shareholders as described below. Defendant Soergel also knowingly, recklessly, or with gross negligence made (or allowed to be made) improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting. Beginning in 2014, Soergel was paid a base salary of $310,000 per year (subject to review and adjustment), an annual bonus in a target amount of 35% of his base salary, and an annual equity award as determined by the Board.

25. Defendant Carrie L. Bourdow was appointed President, CEO, and Board member in October 2018. Prior to her appointment, she served in various senior positions at Trevena since May 2015. She initially joined the Company as SVP, Chief Commercial Officer in May 2015 and was appointed EVP and Chief Operating Officer (COO) in January 2018. Upon joining the Company as a SVP, defendant Bourdow was identified in Trevena's SEC filings as one of the Company's "Executive Officers." Defendant Bourdow breached her fiduciary duties to the Company and its shareholders as described below. Defendant Bourdow also knowingly, recklessly, or with gross negligence made (or allowed to be made) improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting. Between 2016 and 2018, Trevena paid Bourdow as follows:

YEAR	SALARY	OPTION AWARDS	NONEQUITY INCENTIVE PLAN COMPENSATION	OTHER COMPENSATION	TOTAL COMPENSATION
2016	$330,416	$520,534	$116,025	$10,600	$977,575
2017	$341,169	$606,868	$130,413	$10,800	$1,089,250
2018	$418,314	$1,041,309	$146,719	$11,073	$1,779,915

26. Defendant Leon O. Moulder, Jr. has served as a director since November 2011, Chairman of the Board since June 2013, and a Compensation Committee member since at least 2013. Defendant Moulder breached his fiduciary duties to the Company and its shareholders as described below. Defendant Moulder also knowingly, recklessly, or with gross negligence made (or allowed to be made) improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting. Between 2016 and 2018, Trevena paid Moulder $133,209, $100,030, and $100,836, respectively, much of which consisted of Trevena stock option awards.

27. Defendant Michael R. Dougherty has served as a director since August 2013 and Chairperson of the Board's Audit Committee since 2013. Defendant Dougherty breached his fiduciary duties to the Company and its shareholders as described below. Defendant Dougherty also knowingly, recklessly, or with gross negligence made (or allowed to be made) improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting. Between 2016 and 2018, Trevena paid Dougherty $113,209, $80,030, and $80,856, respectively, much of which consisted of Trevena stock awards.

28. Defendant Julie H. McHugh has served as a director since July 2014. Defendant McHugh breached her fiduciary duties to the Company and its shareholders as described below. Defendant McHugh also knowingly, recklessly, or with gross negligence made (or allowed to be

made) improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting. Between 2016 and 2018, Trevena paid McHugh $106,209, $73,030, and $73,856, respectively, much of which consisted of Trevena stock awards.

29. Defendant Jake R. Nunn has served as a director since July 2013 and a member of the Board's Audit Committee since 2013. Defendant Nunn breached his fiduciary duties to the Company and its shareholders as described below. Defendant Nunn also knowingly, recklessly, or with gross negligence made (or allowed to be made) improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting. Between 2016 and 2018, Trevena paid Nunn $103,209, $70,030, and $70,856, respectively, much of which consisted of Trevena stock awards.

30. Defendant Anne M. Phillips has served as a director since December 2014 and a member of the Compensation Committee since 2015. Defendant Phillips breached her fiduciary duties to the Company and its shareholders as described below. Defendant Phillips also knowingly, recklessly, or with gross negligence made (or allowed to be made) improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting. Between 2016 and 2018, Trevena paid Phillips $108,209, $75,030, and $75,856, respectively, much of which consisted of Trevena stock awards.

31. Defendant Barbara Yanni served as a director since July 2014 and a member of the Board's Audit and Compensation Committees since 2014. Defendant Yanni breached her

fiduciary duties to the Company and its shareholders as described below. Defendant Yanni also knowingly, recklessly, or with gross negligence made (or allowed to be made) improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting. Between 2016 and 2018, Trevena paid Yanni $115,709, $82,530, and $83,356, respectively, much of which consisted of Trevena stock awards.

32. Defendant Adam M. Koppel served as a director between September 2014 and his resignation on October 1, 2018, and a member of the Board's Audit Committee from 2014 until his resignation. Defendant Koppel breached his fiduciary duties to the Company and its shareholders as described below. Defendant Koppel also knowingly, recklessly, or with gross negligence made (or allowed to be made) improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting. Between 2016 and 2018, Trevena paid Koppel $105,709, $72,530 and $52,106, respectively, much of which consisted of Trevena stock awards.

33. Defendants Gowen, Moulder, Dougherty, McHugh, Nunn, Phillips, Yanni, Bourdow, and Koppel are collectively referred to as the "Director Defendants." The Director Defendants, along with Soergel and Bourdow are sometimes collectively referred to as the "Individual Defendants." Dougherty, Nunn, and Yanni are collectively referred to as the "Audit Committee Defendants." Moulder, Phillips, and Yanni are collectively referred to as the "Compensation Committee Defendants." Gowen and Soergel are collectively referred to as the "Securities Class Action Defendants."

D. Pertinent Non-Party Board Member

34. Non-Party Scott Braunstein has been a director since September 27, 2018. Since 2015, Braunstein has also been an operating partner of Aisling Capital Management LP ("Aisling"), a private equity firm focusing on healthcare companies. Braunstein was a Healthcare Analyst and Portfolio Manager at J.P. Morgan Asset Management from 2002 to 2014, where he invested in and conducted diligence on a variety of pharmaceutical products and product candidates, pharmaceutical company strategies, business models and management teams, providing stock recommendations for the J.P. Morgan Asset Equity Group. He previously served in a similar role at Everpoint Asset Management, LLC from 2014 to 2015.

IV. DEFENDANTS' DUTIES

A. The Individual Defendants' Fiduciary Duties

35. By reason of their positions as officers and/or directors of Trevena and because of their responsibility to control the business and corporate affairs of the Company, the Individual Defendants owed, and owe, the Company and its shareholders the fiduciary obligations of good faith, loyalty, due care, and candor and were, and are, required to use their utmost ability to control and manage the Company in a just, honest, fair, and equitable manner. Each Individual Defendant owed, and owes, the Company and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company, as well as the highest obligations of fair dealing and not to act in furtherance of their personal interest or benefit.

36. Because of their positions of control and authority as officers and/or directors of Trevena, the Individual Defendants were able to, and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with Trevena, each of the Individual Defendants had

knowledge of material, nonpublic information regarding the Company. In addition, as officers and/or directors of a publicly-held company, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with regard to the Company's business, operations, and prospects so that the market price of the Company's stock would be based on truthful and accurate information.

37. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Trevena and was acting within the course and scope of such agency.

38. To discharge their duties, the Individual Defendants were, and are, required to exercise reasonable and prudent oversight and supervision over the management, policies, practices, and controls of Trevena. By virtue of such duties, the Individual Defendants were, and are, required to, among other things:

a. exercise good faith to ensure that the Company is operated in a diligent, efficient, honest, and prudent manner and in accordance with all applicable laws (including federal and state laws, government rules and regulations, and the Company's Certificate of Incorporation and Bylaws);

b. neither violate nor knowingly permit any officer, director, or employee of Trevena to violate any applicable law, rule, or regulation;

c. remain informed as to the status of Trevena's operations, and upon receipt or notice of information of imprudent or unsound practices, to make a reasonable inquiry in connection thereto and to take steps to correct such conditions or practices;

d. establish and maintain systematic and accurate records and reports of the business and affairs of Trevena and procedures for the reporting of the Company's business and affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

e. implement, maintain, and monitor an adequate, functioning system of internal controls, such that the affairs and operations of Trevena are conducted in accordance with all applicable laws, rules, and regulations; and

f. truthfully and accurately inform and guide investors and analysts with respect to the business operations of the Company.

B. The Individual Defendants' Duties Pursuant to the Company's Code of Conduct and Business Ethics

39. The Individual Defendants were also bound by the Company's Code of Conduct and Business Ethics (the "Code of Conduct"), which applies to all directors, officers, and employees of Trevena.

40. Under a section entitled "Public Disclosures," the Code of Conduct states in relevant part:

> As a public company, the Company must ensure that its filings with and submissions to the SEC and other public communications generally provide full, fair, timely, accurate and understandable disclosure. Company employees engaged in the preparation, submission and communication of these filings ("Public Disclosure Personnel") must endeavor to ensure that the Company's filings, submissions, and communications meet these objectives.

41. Under a section entitled "Research Transparency," the Code of Conduct states in relevant part: "Trevena is committed to providing a high degree of transparency relative to the research that it conducts and sponsors, as well as the results and outcomes of such research."

42. Under a section entitled "Additional Code of Ethics for Senior Financial Officers," which applies to Senior Financial Officers (*i.e.*, the CEO, CFO and others), the Code of Conduct states in relevant part:

> The Senior Financial Officers are responsible for full, fair, accurate, timely and understandable disclosure in the Company's public filings, reports and documents with the SEC and in other publicly disseminated communications such as press releases.

43. Under a section entitled "Communications with Media, Analysts, and the Public," the Code of Conduct states in relevant part:

> Communications with the media, investors, analysts, and the general public can affect the Company's reputation and business. It is important that all communications from the Company be consistent and satisfy all regulatory and legal requirements that may apply.

C. Additional Duties of the Compensation Committee Defendants

44. In addition to the fiduciary duties discussed above, the Compensation Committee Defendants owed specific duties to Trevena under the Charter of the Compensation Committee of the Board of Directors (the "Compensation Charter"). The Compensation Charter states under a section entitled "Responsibilities and Duties" that the committee's principal functions are:

> 2. *Compensation Paid to Executive Officers Other Than the Chief Executive Officer.* The Committee will review and approve the compensation paid to the executive officers of the Company and its affiliates, other than the Company's Chief Executive Officer.
>
> 3. *Compensation Paid to the CEO.* The Committee will review the corporate goals and objectives applicable to the compensation of the Company's Chief Executive Officer, evaluate the Chief Executive Officer's performance in light of these goals and objectives and, based on this review and evaluation, recommend to the Board for approval the compensation of the Chief Executive Officer.
>
> 4. *Compensation Paid to Directors.* The Committee will review and recommend to the Board for approval compensation for service on the Board and the Board committees and recommend any changes to the Board.

45. According to Trevena's 2016, 2017, and 2018 Proxy Statements, the Compensation Committee Defendants' specific responsibilities include the following:

> Effective January 1, 2015, the Board approved the adoption of the ICP. The ICP is designed to provide participants in the plan, including the Company's NEOs, with an incentive in the form of a cash Award to achieve specified corporate and individual objectives during a period of time selected by the Board to which the Award relates.
>
> Each year, the Board, upon the recommendation of the Compensation Committee, establishes major corporate objectives for the coming fiscal year (and the relative weighting of such objectives) (the Corporate Objectives).
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> * * *
>
> At the end of the fiscal year, the Board, upon the recommendation of the Compensation Committee, reviews and approves the level of the Company's achievement against the Corporate Objectives. In addition to its assessment of achievement against each Corporate Objective, the Board may consider Trevena's performance as a whole during the fiscal year, including matters not included in the Corporate Objectives. Following the determination of the corporate achievement, the Committee will consider the individual achievement of each executive officer and Vice President in arriving at the individual Awards, if any, to be made.

D. Additional Duties of the Audit Committee Defendants

46. In addition to the fiduciary duties discussed above, the Audit Committee Defendants owed specific duties to Trevena under the Charter of the Audit Committee of the Board of Directors (the "Audit Charter"). According to the Audit Charter:

> The primary purpose of the Audit Committee (the "Committee") is to act on behalf of the Board of Directors (the "Board") of TREVENA, INC., a Delaware corporation (the "Company") in fulfilling the Board's oversight responsibilities with respect to (i) the Company's corporate accounting and financial reporting processes, (ii) the Company's systems of internal control over financial reporting and audits of its financial statements, (iii) the quality and integrity of the Company's financial statements and reports . . . .
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> * * *
>
> The Committee shall also provide oversight assistance in connection with the Company's legal, regulatory and ethical compliance programs as established by management and the Board.

47. The Audit Charter charges the Audit Committee Defendants with the following responsibilities, among others:

> **13. Management's Discussion and Analysis.** To review and discuss with management and the Auditors, as deemed appropriate, the Company's disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" in its periodic reports to be filed with the SEC.
>
> **14. Disclosure Committee.** To meet with the Disclosure Committee (or a representative thereof), as part of the Committee's regular review of the Company's Form 10-K and Form 10-Q reports (and other filings by the Company with the SEC, when applicable and as deemed necessary, appropriate or desirable by management).
>
> **15. Press Releases.** To review and discuss with management and the Auditors, as deemed appropriate, earnings press releases, and press releases containing information relating to material developments as well as the substance of financial information, information relating to material developments and earnings guidance provided to analysts and rating agencies, which discussions may be general discussions of the type of information to be disclosed or the type of presentation to be made.

48. According to the Company's 2016, 2017, and 2018 Proxy Statements, the Audit Committee Defendants' "Primary Responsibilities" include:

- Representing and assisting the Board in fulfilling its oversight responsibilities regarding the adequacy and effectiveness of internal controls, including financial and disclosure controls and procedures, and the quality and integrity of the Company's financial statements.
- Reviewing with management and the independent registered public accounting firm annual and quarterly financial statements, earnings releases, earnings guidance and significant accounting policies.
- Overseeing compliance with material legal and regulatory requirements.
- Overseeing the Company's enterprise risk management program and advising the Board on financial and enterprise risks.

V. BREACHES OF DUTIES

49. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as officers and directors of Trevena, the

absence of good faith on their part, and a reckless disregard for their duties to the Company that the Individual Defendants were aware, or reckless in not being aware, posed a risk of serious injury to the Company.

50. The Individual Defendants breached their duty of loyalty and good faith by: (i) allowing the Company to press forward with its Phase 3 studies knowing, among other things, that the FDA did not agree with Trevena's proposed dosing, did not agree with its proposed primary endpoint, and did not agree with its proposed noninferiority margin; (ii) allowing each other to cause, or by themselves causing, the Company to make improper statements in Trevena's press releases, public filings, and other public statements relating to the Company's key interactions with the FDA concerning oliceridine, including the March 29, 2016 End-of-Phase 2 meeting; and (iii) failing to properly maintain and/or adequately monitor internal controls which would have prevented the foregoing violations of law. These unlawful practices wasted the Company's assets and caused Trevena to incur substantial damage.

51. The Board members had a duty to properly oversee compliance with Trevena's Code of Conduct. The Code of Conduct, which applies to all directors, officers, and employees, requires "a high degree of transparency relative to the research," full, fair, accurate, timely, and understandable disclosure in the Company's public statements, and that Company communications satisfy all applicable regulatory and legal requirements. As described herein, the Individual Defendants breached their duty of loyalty and good faith by failing to properly oversee compliance with the Code of Conduct by, *inter alia*, making or allowing to be made the improper statements described herein.

52. The Compensation Committee members, and the Board as a whole, had a duty to actively and appropriately oversee, monitor, and confirm the Company's progress towards

critical corporate goals and award incentive compensation to Trevena's executive officers based upon actual progress toward these predetermined objectives. As described herein, the Compensation Committee Defendants breached their duty of loyalty and good faith by failing to properly monitor the Company's progress towards critical corporate goals (including those related to advancing studies and FDA approval of oliceridine) and/or by failing to award incentive compensation based thereon.

53. The Audit Committee members had a duty to review and approve all press releases containing information relating to material developments regarding the Company prior to dissemination including those alleged to be false and misleading herein. They also had a duty to properly oversee the adequacy and effectiveness of the Company's internal controls including those related to public disclosure, the Company's legal, regulatory, and ethical compliance, and the Company's enterprise risk management. As described herein, the Audit Committee Defendants breached their duty of loyalty and good faith by (i) failing to implement an effective oversight system and/or appropriately monitor it, (ii) approving and otherwise allowing the improper statements, (iii) failing to ensure the Company's legal, regulatory, and ethical compliance, and (iv) failing to implement and monitor an effective enterprise risk management system.

54. The Individual Defendants, because of their positions of control and authority as officers and/or directors of Trevena, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein. The Individual Defendants also failed to prevent the other Individual Defendants from taking such improper actions.

VI. CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

55. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct and have acted in concert with

and conspired with one another in furtherance of their common plan or design. In addition to the wrongful conduct alleged herein as giving rise to primary liability, the Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

56. During all times relevant hereto, the Individual Defendants, collectively and individually, initiated a course of conduct that was designed to and did: (i) deceive the investing public, including shareholders of Trevena, regarding the Company's future prospects and the Individual Defendants' management and oversight of Trevena's operations; and (ii) enhance the Individual Defendants' executive and directorial positions at Trevena and the profits, power, and prestige that the Individual Defendants enjoyed as a result of holding these positions. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants, collectively and individually, took the actions set forth herein.

57. The Individual Defendants engaged in a conspiracy, common enterprise, and/or common course of conduct. During this time, the Individual Defendants allowed the Company to engage in flawed Phase 3 studies of oliceridine and allowed the Company to issue improper public statements.

58. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to disguise the Individual Defendants' violations of law, breaches of fiduciary duty, waste of corporate assets, and unjust enrichment, and to conceal adverse information concerning the Company's future prospects.

59. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company to purposefully or recklessly release improper statements. Because the actions described herein occurred under the authority of the

Board, each of the Individual Defendants was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

60. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted in the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

VII. SUBSTANTIVE ALLEGATIONS

A. Company Background

61. Founded in late 2007, Trevena is a clinical-stage biopharmaceutical company. In Trevena's 2014 initial public offering, it transitioned from a private to a public company by selling 9.25 million shares of its common stock for $7 per share on the NASDAQ exchange.

62. Trevena has never generated a profit, nor has it generated revenue from the sale of any product. As it stated in its 2015 SEC Form 10-K filed on March 9, 2016:

> Since our incorporation in late 2007, our operations have included organizing and staffing our company, business planning, raising capital, and discovering and developing our product candidates. We have financed our operations primarily through private placements and public offerings of our equity securities and debt borrowings. As of December 31, 2015, we had an accumulated deficit of $182.5 million. Our net loss was $50.5 million and $49.7 million for the years ended December 31, 2015 and 2014, respectively. Our ability to become and remain profitable depends on our ability to generate revenue or sales. We do not expect to generate significant revenue or sales unless and until we or a collaborator obtain marketing approval for and commercialize oliceridine, TRV027, TRV250 or TRV734.

B. Trevena's Development of Oliceridine

63. Trevena's lead product candidate was and is oliceridine, sometimes known as OLINVO or TRV-130. Oliceridine is a G protein biased mu-opioid receptor ligand for the

management of moderate-to-severe acute pain in hospitals or other controlled clinical settings where intravenous, or IV, administration of opioids is warranted. Trevena claims that oliceridine "when given on-demand, matched morphine efficacy for pain relief with a markedly improved safety and tolerability profile." In other words, according to Trevena oliceridine is as effective as morphine, but with reduced side effects such as "reduced nausea, vomiting, and hypoventilation events."

64. By the end of 2015, Trevena had several drugs in development, the furthest along and most promising being oliceridine. The Company represented its product pipeline in its 2015 Form 10-K as follows:

CNS Portfolio

	Target	Indication	Lead Optimization	Preclinical Development	Phase 1	Phase 2	Phase 3	Ownership
Oliceridine (TRV130)	Mu-receptor	Moderate to Severe Pain	intravenous					Trevena
TRV734	Mu-receptor	Moderate to Severe Pain	oral					Trevena
TRV250	Delta-receptor	Treatment Refractory Migraine	oral					Trevena

Cardiovascular Program

	Target	Indication	Lead Optimization	Preclinical Development	Phase 1	Phase 2	Phase 3	Collaborator
TRV027	Angiotensin II type 1 receptor	Acute Heart Failure	intravenous					Allergan

65. Because oliceridine was the most promising and the closest to FDA approval (and therefore the nearest to generating revenue for the Company), Trevena dedicated most of its research and development resources to the product candidate as reflected in the following chart from the Company's 2015 Form 10-K:

	Year Ended December 31,	
	2015	2014
Personnel-related costs	$ 8,185,768	$ 5,689,895
Stock-based compensation	1,460,061	1,129,245
Oliceridine (TRV130)	16,915,950	14,523,136
TRV027	11,850,728	11,791,851
TRV734	1,616,942	3,408,183

TRV250	1,013,726	1,966,101
Other research and development	3,030,982	2,038,255
	$ 44,074,157	$ 40,546,666

66. On December 2, 2015, the FDA granted fast track designation to oliceridine for the management of moderate-to-severe acute pain where use of IV opioid analgesics is appropriate. Fast track was granted based on the potential ability to provide benefits like those of alternatives with a more favorable adverse event profile. The FDA's "fast track" is a process designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and fill an unmet medical need.

67. On January 19, 2016, the Company issued a press release disclosing that the Company's End-of-Phase 2 meeting with the FDA for oliceridine was "scheduled for later this quarter." Defendant Gowen stated "we also look forward to discussing the oliceridine Phase 3 program with the FDA later this quarter, and remain on track to file an NDA [New Drug Application] for oliceridine in the second half of 2017."

68. On March 3, 2016, the FDA issued non-public written advice to Trevena, asking the Company to "submit amendments to modify all protocols for ongoing clinical trials" to include certain safety assessments, because Trevena's current study saw "QTcF prolongation [which] exceeded the 10-ms regulatory threshold at clinically relevant exposures." The FDA asked Trevena to:

> 1. Conduct safety ECG monitoring at baseline, following the first dose, and periodically thereafter. The timing of ECGs will need to reflect the delayed response relative to time of peak concentrations that was observed in the thorough QT study. Include additional ECG monitoring until ECGs return to baseline in patients discontinued from the trial or requiring dose reduction due to QTc interval prolongation.
>
> 2. Periodic monitoring of electrolytes (subjects already participating in the study with serum potassium, magnesium, or calcium levels outside of the central laboratory's reference range should be carefully monitored and brought to normal values).

3. Propose dose-modification and discontinuation criteria in subjects with posttreatment QTc > 500 ms or post-baseline increases > 60 ms.

69. On March 29, 2016, Trevena executives met in private with the FDA for the End-of-Phase 2 Meeting. The End-of-Phase 2 Meeting did not go well for Trevena. The FDA told the Company during the meeting that it:

- Did not agree with the Company's proposed dosing in its Phase 3 studies. Trevena had proposed 100 mg of daily dosing, but had only studied doses up to 36.8 mg. Further, the FDA informed Trevena that it did not have adequate non-clinical support for its proposed 100 mg doses.
- Did not agree with Trevena's proposed primary endpoint for its Phase 3 study. The FDA said that it was "unclear how a 30% improvement from baseline based on SPID correlates to an improvement in pain intensity scores on the NRS in the proposed setting of acute postoperative pain and if that change is clinically relevant."
- Did not agree with Trevena's proposed non-inferiority (NI) margin for comparing morphine to oliceridine.

70. The FDA further informed Trevena that its safety database must include "at least 350 patients exposed to the highest intended dose for the longest expected duration of use." The FDA told Trevena that "safety database requirements might change if safety signals arise during development that require further evaluation." The FDA also warned that "comparative safety claims must be replicated, adequately justified for clinical relevance, and established in the setting of comparable efficacy between comparators to be considered for inclusion in labeling."

71. Trevena executives who attended the FDA meeting should have left that meeting understanding precisely the what the FDA's concerns were about Trevena's Phase 3 studies,

including that the FDA did not agree with the Company's dosing proposal, proposed primary endpoint, or proposed non-inferiority margin. And, since the FDA warned that any comparative safety claims had to be "established in the setting of comparable efficacy between comparators to be considered for inclusion in labeling," Trevena had significantly diminished prospects of securing such claims given that the FDA did not agree with its method for comparing oliceridine to morphine.

72. The FDA is charged with ensuring that drugs in the marketplace are both safe and effective. To that end, the FDA may approve a drug for market only where there is (a) sufficient information to determine the drug is safe to use as proposed, and (b) substantial evidence the drug will have the effect it is purported to have when used as proposed. 21 U.S.C. § 355(d)(4)(5). According to the FDA: "At the end of Phase 2, the FDA and sponsors try to come to an agreement on how large-scale studies in Phase 3 should be done. . . . These studies gather more information about safety and effectiveness, studying different populations and different dosages and using the drug in combination with other drugs." Concerning Phase 3 studies, the FDA provides:

> **Purpose**: Efficacy and monitoring of adverse reactions
>
> Researchers design Phase 3 studies to demonstrate whether or not a product offers a treatment benefit to a specific population. Sometimes known as pivotal studies, these studies involve 300 to 3,000 participants.
>
> Phase 3 studies provide most of the safety data. In previous studies, it is possible that less common side effects might have gone undetected. Because these studies are larger and longer in duration, the results are more likely to show long-term or rare side effects.

73. The FDA publishes a document entitled "Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants." The version of this document in effect at the time of this meeting stated clearly:

> Before the end of the meeting, FDA attendees and the requested attendees should summarize the important discussion points, agreements, clarifications, and action items. Generally, the requester will be asked to present the summary to ensure that there is mutual understanding of meeting outcomes and actions. FDA staff can add or further clarify any important points not covered in the summary and those items can be added to the meeting minutes.

74. If there were any doubt at all about the FDA's concerns, those doubts were erased when the agency sent written minutes to Trevena from this meeting on April 28, 2016. These written minutes, which were shared only with Trevena, made clear:

- FDA did not agree with the proposed dosing in the Phase 3 studies. The Sponsor proposed dosing up to 100 mg daily (including a 0.75 mg every 1 hour as needed clinician administered dose), but had only studied maximum daily doses of 36.8 mg. Further, the Sponsor did not have adequate non-clinical support for the proposed doses.

- FDA did not agree with the proposed primary endpoint, as it was unclear how a 30% improvement from baseline based on SPID correlates to an improvement in pain intensity scores on the NRS in the proposed setting of acute postoperative pain and if that change is clinically relevant.

- FDA did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine.

- FDA noted that the safety database must include at least 350 patients exposed to the highest intended dose for the longest expected duration of use. It was noted that the safety database requirements might change if safety signals arise during development that require further evaluation.

- Any comparative safety claims must be replicated, adequately justified for clinical relevance, and established in the setting of comparable efficacy between comparators to be considered for inclusion in labeling[.]

- The Applicant provided details of a proposed approach to missing data. This approach included replacing pain scores in the window determined dosing interval described in the label of the rescue medication following rescue with the pain score recorded immediately prior to rescue.

C. The Individual Defendants Make a Series of Improper Statements Regarding the Company's Phase 3 Studies of Oliceridine

75. On May 2, 2016, Trevena issued a press release entitled "Trevena Announces Successful End-of-Phase 2 Meeting with FDA and Outlines Phase 3 Program for Oliceridine," which stated as follows:

> Trevena, Inc. (NASDAQ: TRVN), a clinical stage biopharmaceutical company focused on the discovery and development of biased ligands targeting G protein coupled receptors, today announced the successful completion of the End-of-Phase 2 Meeting process with the United States Food and Drug Administration (FDA). The company has reached general agreement with the FDA on key elements of the Phase 3 program to support a New Drug Application (NDA) for oliceridine (TRV130), to which the FDA has granted Breakthrough Therapy designation.
>
> "We are very pleased with the outcome of our End-of-Phase 2 discussion with the FDA," said Maxine Gowen, Ph.D., chief executive officer. "We appreciate the valuable guidance the FDA has provided, and look forward to continuing a constructive relationship as we advance our Phase 3 registration program. We remain focused on bringing oliceridine to market as a new and potentially differentiated analgesic for patients and caregivers seeking alternatives to conventional opioids."
>
> **End-of-Phase 2 meeting**
>
> The FDA agreed that pivotal efficacy trials in bunionectomy and abdominoplasty patients include appropriate patient populations to support an indication for moderate to severe acute pain. The agency also confirmed the need for at least 1,100 patients exposed to oliceridine across the development program for the purposes of evaluating safety and tolerability. This database should include a sufficient number of patients with higher exposures and longer durations of oliceridine therapy. In addition, general agreement was reached on the company's planned clinical, nonclinical, clinical pharmacology, and chemistry, manufacturing and control (CMC) activities to support the planned NDA.
>
> **Overview of the Oliceridine Phase 3 program**
>
> - The oliceridine Phase 3 program includes two pivotal efficacy trials evaluating moderate-to-severe acute pain: the APOLLO-1 study will evaluate pain for 48 hours following bunionectomy, and the APOLLO-2 study will evaluate pain for 24 hours following abdominoplasty. In each trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) for the

management of their post-operative pain. Each study will enroll approximately 375 patients, allocated equally across study arms.

- The primary endpoint for both APOLLO studies will be a responder analysis proposed by the company comparing active treatment arms to placebo. A responder is defined as a patient experiencing a sum of pain intensity difference (SPID) at the end of the treatment period that corresponds to at least a 30% improvement from baseline without early discontinuation and without rescue pain medication.

- Secondary endpoints in both APOLLO studies will include comparisons of oliceridine efficacy, safety, and tolerability to morphine. A respiratory safety endpoint will measure prevalence and duration of hypoventilation, which will be a clinical assessment as in the company's Phase 2b abdominoplasty study.

- The APOLLO study designs were informed in part by the company's Phase 2b abdominoplasty study, which also used PCA dosing. Powering assumptions included similar performance of PCA-administered oliceridine in both APOLLO studies as was observed in the Phase 2b study. In a post-hoc evaluation using the Phase 3 responder analysis, both doses in the company's Phase 2b study in abdominoplasty yielded analgesic efficacy similar to morphine, and significantly higher than placebo ($p \leq 0.0005$ for both oliceridine treatment arms). In addition, using the Phase 3 respiratory safety endpoint, both doses in the company's Phase 2b study showed significantly less respiratory safety burden for oliceridine than morphine ($p \leq 0.0003$ for both oliceridine treatment arms).

- The development program will include at least 1,100 patients exposed to oliceridine. The on-going open-label ATHENA-1 safety study is enrolling patients experiencing pain as a result of either a medical diagnosis or surgery. In this study, patients may receive oliceridine as-needed either as an intermittent bolus or via PCA device, with doses and durations appropriate to manage their pain.

Both APOLLO-1 and APOLLO-2 are expected to start in the second quarter of this year, and the company expects to report top-line data in the first quarter of 2017. The company continues to expect to file an NDA for oliceridine in the second half of 2017. The company also continues to expect that its available cash and investments will be sufficient to fund operations into 2018.

(Underline emphasis added).

76. On the same day, Trevena made an investor presentation, which included the following slides:

Successful outcome for the end-of-phase 2 meeting for the oliceridine program

- General agreement was reached to move oliceridine in to Phase 3
- General agreement was reached that the oliceridine Phase 3 program could support an approval for the target indication
  - *Management of moderate-to-severe acute pain where parenteral therapy is warranted*

- Key elements of Phase 3 program:
  - Two pivotal efficacy studies with PCA dosing to support potential finding of efficacy
  - Bunionectomy and abdominoplasty populations appropriate for target indication
  - Safety database with PCA and bolus dosing ≥1,100 patients
    - Including a sufficient number of patients with higher exposures and longer durations of oliceridine therapy
  - Key clinical pharmacology, nonclinical toxicology, CMC activities to support NDA

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Pivotal efficacy studies to support potential approval

- Two pivotal studies: same surgical models as in Phase 2
  - APOLLO-1: 48 hour treatment following bunionectomy
  - APOLLO-2: 24 hour treatment following abdominoplasty
  - Each study will include 375 patients, 75/group

- Primary endpoint: efficacy of oliceridine vs. placebo

- Secondary endpoints: oliceridine vs. morphine
  - Efficacy, including pain intensity difference and time to onset
  - Safety, including respiratory safety burden based on hypoventilation events
  - Tolerability, including nausea and vomiting

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Pivotal efficacy studies: primary endpoint

- Same measure as Phase 2: pain intensity assessed with a visual analog scale
- Phase 3 will use a responder analysis as proposed by Trevena
  - Defined as ≥30% improvement in sum of pain intensity difference from baseline (SPID) *without* early discontinuation and *without* rescue pain medication
  - Rationale:
    - More straightforward clinical interpretation than pain intensity difference
    - Incorporates an element of safety/tolerability
    - High power based on post-hoc analysis of Phase 2b abdominoplasty data

Post-hoc analysis of phase 2b abdominoplasty data using Phase 3 primary endpoint

	Placebo (n = 39) volume matched	Oliceridine (n = 39) 1.5 mg load, 0.1 mg demand	Oliceridine (n = 39) 1.5 mg load, 0.35 mg demand	Morphine (n = 83) 4.0 mg load, 1.0 mg demand
Responders, n (%)	12 (30.8%)	25 (64.1%)	28 (71.8%)	55 (66.3%)
p-value vs. placebo		0.0005	0.0004	0.0003

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Summary

- Successful end-of-phase 2 meeting
  - Appropriate to move oliceridine to Phase 3
  - Agreed upon key elements of Phase 3 program
  - Collaborative discussion with FDA
- Phase 3 program overview
  - APOLLO studies designed to support approval and differentiation
    - Endpoints and analysis are well informed by the Phase 2 program
  - ATHENA-1 study is underway
  - APOLLO studies to commence this quarter
- Breakthrough Therapy designation offers opportunity for ongoing dialogue

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77. On the same day, defendants Gowen and Soergel conducted a conference call with analysts and investors where the above slides were presented. During the call, defendant Gowen stated: "We welcome the opportunity to work with the FDA to finalize our Phase 3 plans. I am pleased to report that we had a very productive and collaborative and successful discussion of our oliceridine program with the FDA. This was not only helpful as we transition the program into Phase 3, but I'm sure will be invaluable as we continue our conversation throughout the NDA."

78. Trevena repeated many of these same comments in a press release it issued on May 5, 2016 entitled "Trevena Reports First Quarter 2016 Financial Results and Provides Corporate Update." The release stated in pertinent part:

> Trevena, Inc. (NASDAQ: TRVN), a clinical stage pharmaceutical company focused on the discovery and development of biased ligands targeting G protein coupled receptors (GPCRs), today announced financial results for the quarter ended March 31, 2016 and provided an update regarding its ongoing clinical programs.
>
> "The first quarter set the stage for a critical year in Trevena's evolution," said Maxine Gowen, Ph.D., chief executive officer. "We had a successful End-of-Phase 2 discussion of oliceridine with the FDA, and look forward to completing our ongoing Phase 3 program aimed at both approval and differentiation of oliceridine for moderate to severe acute pain. In addition, we completed enrollment of the BLAST-AHF Phase 2b Study of TRV027 for acute heart failure and expect to present topline data later this month."
>
> **First Quarter and Recent Highlights** [emphasis in original]
>
> - **Received Breakthrough Therapy Designation for oliceridine.** In February, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to the company's lead product candidate, intravenous oliceridine (TRV130), for the management of moderate-to-severe acute pain. Breakthrough Therapy designation is granted by the FDA to new therapies intended to treat serious conditions, and for which preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. The company believes this is the first Breakthrough Therapy designation for a pain therapy.

- **Conducted a successful End-of-Phase 2 meeting for oliceridine with the FDA and announced details of the Phase 3 clinical program.** Earlier this week, the company announced that it had reached agreement with the FDA on key elements of the Phase 3 program to support a New Drug Application (NDA) for oliceridine. The company also provided additional details of the Phase 3 clinical program, which will include two 375-patient, randomized, double-blind, placebo- and active-controlled, pivotal efficacy trials: the APOLLO-1 study, which will evaluate pain for 48 hours following bunionectomy; and the APOLLO-2 study, which will evaluate pain for 24 hours following abdominoplasty. In each trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) for the management of their post-operative pain, with approximately 75 patients enrolled per study arm. The primary endpoint for both APOLLO studies will be a responder analysis comparing active treatment arms to placebo. Secondary endpoints in both APOLLO studies will include comparisons of oliceridine efficacy, safety, and tolerability to morphine.

  In January, the company initiated the Phase 3 clinical program with the enrollment of patients in the open label ATHENA study, which is evaluating the safety and tolerability of oliceridine in patients with moderate-to-severe acute pain caused by medical conditions or surgery. Patients will be treated with oliceridine on an as-needed basis via IV bolus, PCA administration, or both, as determined by the investigator.

  The company expects to start the APOLLO studies in the second quarter of this year, and to report top-line data from these studies in the first quarter of 2017. The company continues to expect to file an NDA in the second half of 2017.

(Underline emphasis added unless noted).

79. Many of the statements made on May 2, 2016 and repeated on May 5, 2016 as described above, were materially false and misleading and omitted to disclose material facts necessary to make the statement made not materially false or misleading. The table below summarizes these statements, and explains why each statement was materially false or misleading when made and the omitted material facts:

Statement	**Why the Statement Was Materially False or Misleading**
Trevena: "The company has reached general agreement with the FDA on key elements of the Phase 3 program to support a New Drug Application (NDA) for oliceridine (TRV130)." ¶ 75.	Trevena's investor presentation lists "key elements" of the Phase 3 program, among which are: two pivotal efficacy studies with PCA dosing to support potential finding of efficacy; and safety database with PCA and bolus dosing $\geq$ 1,100 patients, including a sufficient number of patients with higher exposures and longer durations of oliceridine therapy. ¶ 76. Trevena failed to disclose that the FDA: instructed Trevena to modify all protocols for ongoing clinical trials to include certain safety assessments; did not agree with the proposed dosing in the Phase 3 studies; did not agree with the proposed primary endpoint; did not agree with the proposed non-inferiority margin for comparing morphine to oliceridine; required a safety database of at least 350 patients exposed to the highest intended dose for the longest expected duration of use; required any comparative safety claims to be replicated, adequately justified for clinical relevance, and established in the setting of comparable efficacy between comparators to be considered for inclusion in labeling. ¶¶ 67, 74. The foregoing disagreements and issues raised by the FDA relate directly to the pivotal efficacy studies and the primary and secondary endpoints thereto, as well as the safety study. The omission of these critical disagreements regarding the key elements of the Phase 3 program rendered Trevena's statements materially false and misleading.

Trevena: "Trevena Announces Successful End-of-Phase 2 Meeting with FDA . . ." ¶ 75. Trevena: "Trevena . . . today announced the successful completion of the End-of-Phase 2 Meeting process with the United States Food and Drug Administration (FDA)." ¶ 75. Gowen: "We are very pleased with the outcome of our End-of-Phase 2 discussion with the FDA . . . ." ¶ 75. Gowen: "[W]e had a very productive and collaborative and successful discussion of our oliceridine program with the FDA." ¶ 77.	In light of defendants' statement that "The Company had reached general agreement with the FDA on key elements of the Phase 3 program" a reasonable person, reading defendants' statements concerning the success of the End-of-Phase 2 meeting and being "very pleased" with the outcome of the meeting, would understand that Trevena's executives believed that the FDA did in fact agree with the key elements of the Phase 3 program, and all that stood in the way of gaining approval was successfully implementing the program as it had been presented to the FDA. Despite being aware of the FDA's disagreements regarding the key elements of the Phase 3 program, Trevena and defendant Gowen made statements concerning the success of the End-of-Phase 2 Meeting" and being "very pleased" with the End-of-Phase 2 discussions with the FDA. The omitted facts, known to defendants, were necessary to make the statements concerning the success of the End-of-Phase 2 meeting with the FDA not materially misleading.
Trevena: "[Safety] database should include a sufficient number of patients with higher exposures and longer durations of oliceridine therapy." ¶ 75.	Trevena omitted to disclose that the FDA informed them "that the safety database must include at least 350 patients exposed to the highest intended dose for the longest expected duration of use." ¶ 74. Trevena's materially incomplete description of the FDA's safety database requirements are particularly misleading given that the FDA did not agree with Trevena's proposed dosing as the Company had not previously studied doses even half of the levels proposed for Phase 3 and did not have adequate non-clinical support for the proposed dosing. ¶ 74. Investors were thus unaware that the FDA had set forth strict minimum requirements for the safety database, why those requirements were set, and that satisfying those

	requirements was critical to Trevena's chances for approval.
Trevena: "The primary endpoint for both [Phase 3 pivotal efficacy] studies will be a responder analysis proposed by the company comparing active treatment arms to placebo. A responder is defined as a patient experiencing a sum of pain intensity difference (SPID) at the end of the treatment period that corresponds to at least a 30% improvement from baseline without early discontinuation and without rescue pain medication." ¶ 75.	Trevena omitted to disclose that the FDA "did not agree with the proposed primary endpoint, as it was unclear how a 30% improvement from baseline based on SPID correlates to an improvement in pain intensity scores on the NRS in the proposed setting of acute postoperative pain and if that change is clinically relevant." ¶ 74. Trevena listed the pivotal efficacy trials to which the primary endpoint applied as a "key element" of the Phase 3 program in its investor presentation (¶ 76), rendering the statement that it reached general agreement with the FDA on "key elements of the Phase 3 program" materially false and misleading.
Trevena: "Secondary endpoints in both [Phase 3 pivotal efficacy] studies will include comparisons of oliceridine efficacy, safety, and tolerability to morphine. A respiratory safety endpoint will measure prevalence and duration of hypoventilation, which will be a clinical assessment as in the company's Phase 2b abdominoplasty study." ¶ 75.	Trevena failed to disclose that the FDA "did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine" and that "[a]ny comparative safety claims must be replicated, adequately justified for clinical relevance, and established in the setting of comparable efficacy between comparators to be considered for inclusion in labeling." ¶ 74. These secondary endpoints applied to the pivotal efficacy trials listed as a "key element" of the Phase 3 program (¶ 76) on which Trevena claimed to have reached agreement with the FDA. Omitting to disclose these disagreements concerning key elements of the Phase 3 trials and issues raised by the FDA rendered Trevena's description of the secondary endpoints materially false and misleading.

Trevena: "[Phase 3 pivotal efficacy] study designs were informed in part by the company's Phase 2b abdominoplasty study, which also used PCA dosing. Powering assumptions included similar performance of PCA-administered oliceridine in both APOLLO studies as was observed in the Phase 2b study. In a post-hoc evaluation using the Phase 3 responder analysis, both doses in the company's Phase 2b study in abdominoplasty yielded analgesic efficacy similar to morphine, and significantly higher than placebo ($p \leq 0.0005$ for both oliceridine treatment arms). In addition, using the Phase 3 respiratory safety endpoint, both doses in the company's Phase 2b study showed significantly less respiratory safety burden for oliceridine than morphine ($p \leq 0.0003$ for both oliceridine treatment arms)." ¶ 75.	Trevena omitted to disclose that the FDA "did not agree with the proposed dosing in the Phase 3 studies. The Sponsor proposed dosing up to 100 mg daily (including a 0.75 mg every 1 hour as needed clinician administered dose), but had only studied maximum daily doses of 36.8 mg. Further, the Sponsor did not have adequate non-clinical support for the proposed doses." ¶ 74. Trevena also omitted to disclose that the FDA "did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine[.]" ¶ 74. Omitting to disclose these disagreements concerning key elements of the Phase 3 trials rendered Trevena's description of the Phase 3 study designs materially false and misleading, particularly in light of the Company's claim that it had reached general agreement with the FDA on "key elements" of the Phase 3 program.
Trevena: "The development program will include at least 1,100 patients exposed to oliceridine. The on-going open-label ATHENA-1 safety study is enrolling patients experiencing pain as a result of either a medical diagnosis or surgery. In this study, patients may receive oliceridine as-needed either as an intermittent bolus or via PCA device, with doses and durations appropriate to manage their pain." ¶ 75.	Trevena omitted to disclose that the FDA did not agree with the proposed dosing in the Phase 3 studies and that as a result, the FDA set minimum criteria for the safety database – requiring at least 350 patients exposed to the highest intended dose for the longest expected duration of use. ¶ 74. Furthermore, the Company omitted to disclose that the ATHENA-1 study was designed in a manner that would prevent it from meeting the FDA's requirement of a safety database that includes at least 350 patients exposed to the highest intended dose for the longest expected duration of use. As a result of these omissions of material facts, Trevena's description of the safety study was materially false and misleading, particularly in light of the Company's claim that it had reached general agreement with the FDA on "key elements" of the Phase 3

	program.

80. During the May 2, 2016 conference call, defendant Gowen told investors "Our confidence in the plans we presented to the agency going into the end of Phase 2 meeting, led us to initiate much of the preparatory work for our pivotal efficacy studies ahead of the meeting; and I'm happy to share that, that decision has paid off and we will be commencing both of our pivotal efficacy studies this quarter." Later in the call, Gowen reiterated, "we did quite a lot of the study start up at risk because we were fairly confident in our pivotal study trial design that we submitted to the FDA. We're very happy now that we did that because it really allows us to start very quickly now."

81. Defendants took a calculated gamble and lost it. They bet the FDA would agree with their proposals for the Phase 3 studies and, as Gowen admitted, they did a lot of work "ahead of the meeting" "at risk." Rather than admit their failure and waste of time, money, and effort, the Individual Defendants simply moved forward with the work they already started despite the FDA's disagreements with them. While Trevena was representing to investors about

their supposedly "successful" meeting with the FDA, they were also lobbying the agency about Trevena's proposed endpoint and responder definition, which Trevena knew the FDA did not agree with. Trevena's hubris led them to set up the Phase 3 program at risk so that they would be able to move forward immediately after the end of Phase 2 meeting. When the FDA disagreed with the key elements of Trevena's Phase 3 program, the Company attempted to push its plan through rather than take the time and resources to redesign the Phase 3 program to the FDA's satisfaction.

82. A reasonable person, reading defendant Gowen's statements concerning the benefits of having frontloaded the Phase 3 program design prior to the End-of-Phase 2 meeting, would understand that Trevena's executives believed that the FDA agreed with the key elements of their Phase 3 program, and all that stood in the way of securing approval for oliceridine was successfully implementing the program as it had been presented to the FDA. Gowen omitted the known material facts, that the FDA disagreed with the key elements of the Phase 3 program, which were necessary to make her statement regarding the benefits of having initiated the Phase 3 program design ahead of the End-of-Phase 2 meeting not misleading. Rather than "allow[ing] [Trevena] to start very quickly now," the real facts were that Trevena had already started—at risk—a Phase 3 program which the FDA disagreed with, and Trevena would not be able or willing to modify the program as a result of the FDA's disagreements.

83. Indeed, just days after touting the success and agreement with the FDA, on May 6, 2016, unbeknownst to investors, Trevena submitted to the FDA a justification for their proposed responder definition, which the FDA had previously rejected.

84. Omitting to disclose the FDA's disagreement with Trevena's proposed primary endpoint while concealing Trevena's ongoing attempt to justify its rejected primary endpoint

rendered the statements concerning the benefits of preparing the Phase 3 study at risk, set forth in paragraphs 80 and 81, materially false and misleading.

85. Defendants Gowen and Soergel apparently attended the March 29, 2016 meeting with the FDA and received and reviewed the FDA's minutes from that meeting. Soergel stated on May 2 "we held our end of Phase 2 meeting at the end of March and we recently received the final meeting minutes from the FDA." Similarly, Gowen stated "we've had a very successful end of Phase 2 meeting with the FDA. We heard that it is appropriate to move oliceridine into Phase 3 . . . ."

86. Even if neither Gowen nor Soergel attended the March 29, 2016 End-of-Phase 2 meeting in person, they were reckless in discussing what occurred at the meeting, what the FDA purportedly agreed with without first reviewing the minutes of the meeting that were sent to Trevena. As a clinical stage biopharmaceutical company dependent on a single drug obtaining approval from the FDA, its senior officers either knew of what actually happened at the End-of-Phase 2 meeting and read the meeting minutes or discussed what transpired at the meeting in reckless disregard for the truth.

87. On May 16, 2016, Trevena announced that its only other major drug candidate, TRV-027, "failed to meet either the primary or secondary endpoints" during its Phase 2 trial. Trevena made clear to investors that, as a result, it "expects to focus its efforts on its lead Phase 3 oliceridine pain program and its earlier stage programs," and that there were no other drugs far along in the development pipeline for Trevena besides oliceridine.

88. On June 8, 2016, Trevena issued a press release entitled "Trevena, Inc. Announces First Patients Enrolled in the APOLLO-1 and APOLLO-2 Phase 3 Pivotal Efficacy Studies of Oliceridine in Acute Pain." In part, the press release stated:

> Trevena, Inc. (NASDAQ: TRVN), a clinical stage biopharmaceutical company focused on the discovery and development of biased ligands targeting G protein coupled receptors, today announced the enrollment of the first patients in the Phase 3 APOLLO-1 and APOLLO-2 studies of oliceridine in patients suffering moderate to severe acute pain following bunionectomy and abdominoplasty, respectively.
>
> "We are pleased to announce the start of the APOLLO studies, which we designed both to support approval of oliceridine and to confirm the potential differentiation of oliceridine from conventional opioids," commented Maxine Gowen, Ph.D., chief executive officer. ***"The trials recapitulate many features of our successful Phase 2 studies, with refinements based on the full Phase 2 data set that we believe strengthen the study designs and improve our probability of success. Together with the ongoing ATHENA Phase 3 safety study, we believe the APOLLO studies position us to deliver a robust data package to support regulatory approval and commercial success."***
>
> The company continues to expect to report top-line data from both APOLLO studies in the first quarter of 2017, and to file an NDA for oliceridine in the second half of 2017. The company also continues to expect that its available cash and investments will be sufficient to fund operations into 2018.
>
> **About the APOLLO-1 and APOLLO-2 Studies**
>
> Both APOLLO trials are phase 3, multicenter, randomized, double-blind, placebo- and active-controlled studies of oliceridine for the treatment of moderate to severe acute pain. The APOLLO-1 study will evaluate pain for 48 hours following bunionectomy, and the APOLLO-2 study will evaluate pain for 24 hours following abdominoplasty. In each trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) device for the management of their post-operative pain. Each study will enroll approximately 375 patients, allocated equally across study arms. ***The primary objective in each study is to evaluate the analgesic efficacy of oliceridine compared to placebo. Secondary endpoints will include comparisons of oliceridine efficacy, safety, and tolerability to morphine.***

(Emphasis added).

89. Defendant Gowen's statement that "we believe the APOLLO studies position us to deliver a robust data package to support regulatory approval and commercial success," was misleading and contained a material omission, in that the statement fails to explain that the FDA had: instructed Trevena to modify all protocols for ongoing clinical trials; disagreed with the proposed dosing due to a lack of prior clinical data and non-clinical support for the proposed

doses; and disagreed with the proposed non-inferiority margin for comparing morphine to oliceridine, as described above.

90. Trevena's description of the primary and secondary endpoints of the study was misleading and contains a material omission, in that the statement fails to explain that the FDA disagreed with the use of the primary endpoint proposed by Trevena, the proposed dosing regimen, as well as the methods by which Trevena intended to prove its proposed secondary endpoints as described above.

91. Also, on June 8, 2016, defendant Gowen presented on behalf of Trevena at the Jefferies Healthcare Conference. During her opening remarks, Gowen stated "So, we had an end of Phase 2 meeting with the FDA at the very end of March. And we reached agreement with them that we have shown sufficient data to move into Phase 3. The program that we proposed to them they agreed would support an approval – could support, I should say given that the data are correct, could support an approval for the target indication." Gowen further stated: "The key elements of the Phase 3 program are two pivotal efficacy studies with PCA dosing as I – in the study that I just showed you in Phase 2, to support efficacy. . . . And this is what allows us to get this broad label."

92. Gowen's statement regarding the FDA's comments at the End-of-Phase 2 meeting at the end of March 2016 were materially false and misleading. The statement that the FDA "agreed" that the "program [Trevena] proposed to them . . . could support an approval for the target indication" is directly contradicted by the FDA's minutes from that Phase 2 meeting, where the FDA informed Trevena that it did not agree with the proposed dosing or primary endpoint for the pivotal efficacy studies, which defendant Gowen herself described as "key elements of the Phase 3 program."

93. Furthermore, defendant Gowen's description of the Phase 3 efficacy studies contained material omissions in that the statements described the studies as being able to get Trevena a "broad label" from the FDA without disclosing that the FDA, during its March 2016 meeting with Trevena, stated that "[a]ny comparative safety claims must be replicated, adequately justified for clinical relevance, and established in the setting of comparable efficacy between comparators to be considered for inclusion in labeling," as described above. At the same March 2016 meeting, the FDA also stated that it "did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine." Since the FDA disagreed with Trevena's proposed method for comparing morphine to oliceridine, and informed the Company that comparative safety claims had to be established in the setting of comparable efficacy between comparators [*i.e.,* morphine] to be considered for inclusion on the label, Trevena's chances of obtaining a "broad label" from the FDA were far from likely. This is directly contrary to what Trevena presented to investors.

94. On June 21, 2016, defendant Soergel presented at the JMP Securities Life Sciences Conference. During his opening remarks, Soergel stated "The Phase 3 timing and expectations, as you can see here, we've initiated our Phase 3 program. The ATHENA study was initiated in the first quarter. The two pivotal efficacy trials were initiated in the second quarter. We expect the data from our Phase 3 pivotal efficacy studies in the first quarter of 2017 with an NDA submission in the second half of 2017. And hopefully, we can get this important new drug to patients quickly."

95. This statement was misleading and contained a material omission in that Soergel stated that Trevena expected to submit its NDA in the second half of 2017 without disclosing that the FDA had: previously informed Trevena of the need to modify all protocols for ongoing

clinical trials; did not agree with the proposed dosing; did not agree with the proposed primary endpoint; did not agree with the proposed non-inferiority margin for comparing morphine to oliceridine; warned that comparative safety claims would have to satisfy stringent requirements to be considered for inclusion in labeling; and had set forth strict criteria for the safety database due to concerns about Trevena's proposed dosing, greatly decreasing the likelihood of success of that NDA.

96. On August 3, 2016, Trevena issued a press release announcing its second quarter 2016 financial results. The press release stated in part:

> "This quarter marked an important milestone for the company's oliceridine program with the initiation of our two Phase 3 pivotal efficacy trials," said Maxine Gowen, Ph.D., chief executive officer. ***"Following our successful End-of-Phase-2 and Breakthrough Therapy designation meeting with the FDA in the first quarter, we were able to rapidly initiate the pivotal efficacy trials, which are enrolling well."***
>
> **Second Quarter and Recent Highlights** [emphasis in original]
>
> Enrolled first patients in APOLLO-1 and APOLLO-2 Phase 3 trials of oliceridine. In June, the company announced the enrollment of the first patients in the APOLLO-1 and APOLLO-2 pivotal Phase 3 efficacy studies. APOLLO-1 is studying patients suffering moderate to severe pain for 48 hours after undergoing bunionectomy, while APOLLO-2 is studying patients suffering moderate to severe pain for 24 hours after undergoing abdominoplasty; both are 375-patient, multicenter, randomized, double-blind, placebo- and active-controlled studies. Patients are randomized to receive placebo, morphine, or one of three oliceridine regimens, all dosed as needed via patient-controlled analgesia (PCA) device for the management of their post-operative pain, with approximately 75 patients per study arm. ***The primary objective of both trials is to evaluate the analgesic efficacy of oliceridine versus placebo. Secondary endpoints compare the efficacy, safety, and tolerability of oliceridine to morphine. The company continues to expect to release top-line data in the first quarter of 2017 and to file an NDA in the second half of 2017.***

(Emphasis added unless noted).

97. The statement made by defendant Gowen regarding Trevena's "successful End-of-Phase 2 and Breakthrough Therapy designation meeting with the FDA in the first quarter,"

was materially false and misleading in that the End-of-Phase 2 meeting was not successful, given that the meeting resulted in the FDA informing Trevena that it did not agree with the proposed dosing, the proposed primary endpoint, or the proposed non-inferiority margin for comparing morphine to oliceridine. The FDA had also warned that comparative safety claims would have to satisfy stringent requirements to be considered for inclusion in labeling, and had set forth strict criteria for the safety database due to concerns about Trevena's proposed dosing.

98. The description Trevena provided of the endpoints of their Phase 3 studies was misleading and contained material omissions in that the statement failed to disclose that the FDA had disagreed with Trevena's use of the endpoint proposed by Trevena.

99. Trevena's statement that it "continues to expect to . . . file an NDA in the second half of 2017" was misleading and omitted to disclose material facts as the statement failed to disclose that the FDA had: previously informed Trevena of the need to modify all protocols for ongoing clinical trials; did not agree with the proposed dosing; did not agree with the proposed primary endpoint; did not agree with the proposed non-inferiority margin for comparing morphine to oliceridine; warned that comparative safety claims would have to satisfy stringent requirements to be considered for inclusion in labeling; and had set forth strict criteria for the safety database due to concerns about Trevena's proposed dosing, and was thus unlikely to approve Trevena's NDA.

100. On November 3, 2016, Trevena issued a press release announcing its third quarter 2016 financial results. The press release stated in part:

> "This quarter saw important progress for our company, with continued execution of our Phase 3 program for oliceridine. We had extensive engagement with the medical community to discuss the challenges of acute pain management in the hospital and how oliceridine may provide an important treatment option to patients and physicians," said Maxine Gowen, Ph.D., chief executive officer. "We look forward to sharing top-line data from both Phase 3 APOLLO pivotal

efficacy studies in the first quarter of 2017, and filing an NDA in the second half of next year."

Third Quarter and Recent Highlights [Emphasis in original]

- APOLLO-1 and APOLLO-2 Phase 3 efficacy trials of oliceridine remain on track for first quarter 2017 top-line data release. The APOLLO-1 trial includes patients suffering moderate to severe pain after undergoing bunionectomy, while the APOLLO-2 trial includes patients suffering moderate to severe pain after undergoing abdominoplasty; both are 375-patient, multicenter, randomized, double-blind, placebo- and active-controlled studies. ***Patients are randomized to receive placebo, morphine, or one of three oliceridine regimens, all dosed as needed via patient-controlled analgesia (PCA) device*** for the management of their post-operative pain, with approximately 75 patients per study arm. ***The primary objective of both trials is to evaluate the analgesic efficacy of oliceridine versus placebo. Secondary endpoints compare the efficacy, safety, and tolerability of oliceridine to morphine.***

- ***Patient enrollment remains on track in the ATHENA multi-procedure safety study of oliceridine to support NDA filing in 2H 2017.*** This trial complements the APOLLO studies and aims to evaluate the safety and tolerability of oliceridine in patients with moderate to severe acute pain caused by a broad range of medical conditions or surgeries. Patients are treated on an as-needed basis via IV bolus, PCA administration, or both, as determined by the investigator.

(Emphasis added unless noted).

101. The description Trevena provided of the dosing for the Phase 3 studies was misleading and contained material omissions in that the statement failed to disclose that the FDA had disagreed with Trevena's proposed dosing in the Phase 3 studies.

102. Likewise, the description Trevena provided of the primary and secondary endpoints of the Phase 3 studies was misleading and contained material omissions in that the statement failed to disclose that the FDA had disagreed with Trevena's use of the primary and secondary endpoints proposed by the Company.

103. Trevena's statement that "[p]atient enrollment remains on track in the ATHENA multi-procedure safety study of oliceridine to support NDA filing in 2H 2017" and subsequent

description of the safety study was misleading and contained material omissions in that the statement failed to disclose that the FDA had instructed Trevena to "modify all protocols for ongoing clinical trials" to include certain safety assessments. The statement also failed to disclose that the FDA had provided explicit minimum criteria for the safety database due to concerns about Trevena's proposed dosing regimen. As discussed in ¶¶ 149-50, below, Trevena failed to implement the safety assessments as instructed by the FDA and failed to ensure that the safety database satisfied the FDA's minimum criteria, and was thus unlikely to gain approval for the NDA.

104. On November 8, 2016, unbeknownst to investors and the marketplace, Trevena held a teleconference with the FDA concerning the agency's disagreement with Trevena's proposed method for evaluating the respiratory safety of oliceridine as compared to morphine. The agency sent written minutes to Trevena from this meeting on December 19, 2016. These written minutes, which were shared only with Trevena, stated directly:

- FDA did not agree with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine because the definition of Respiratory Safety Events (RSEs) was not clearly defined and the determination of the presence of an RSE relied largely on clinical acumen. Even though the parameters proposed in the evaluation of an RSE (respiratory rate, oxygen saturation, and MRPSS somnolence/sedation scores) are well accepted criteria used for the assessment of patients at risk for experiencing an RSE, it is unclear that a small change in these parameters is of clinical significance. Trevena was told to specify a clinically meaningful definition of an RSE, such as patients who require a clinical intervention after meeting a specific criterion (e.g., naloxone administration and/or oxygen administration with a reduction in oxygen saturation). Further, FDA did not agree with inclusion of sedation and somnolence in the RSE definition.

- FDA stated that the statistical model proposed to evaluate the respiratory safety of oliceridine incorporates both the population prevalence of RSEs and the population conditional mean cumulative duration of RSEs to describe respiratory safety burden (RSB). Based on this model, a small change in event duration could result in a statistically significant result

> without clinical significance. In addition, the RSB endpoint is difficult to interpret and apply directly to clinical practice. Trevena was asked to analyze and report event duration separately from the event prevalence.

105. On January 4, 2017, Trevena issued a press release entitled "Trevena Completes Enrollment of Phase 3 APOLLO Pivotal Efficacy Trials of Oliceridine for Moderate-to-Severe Acute Pain." In part, the press release stated:

> Trevena, Inc. (NASDAQ:TRVN) today announced that it has completed enrollment of its Phase 3 APOLLO-1 and APOLLO-2 pivotal efficacy studies of oliceridine (TRV130) in moderate-to-severe acute pain following bunionectomy and abdominoplasty, respectively.
>
> "We are pleased to have completed enrollment in these important studies and to confirm that the APOLLO trials remain on schedule to report top-line results in the first quarter of 2017," said Maxine Gowen, Ph.D., chief executive officer. "We look forward to sharing these data when they become available."
>
> ***The APOLLO studies were designed based on the Phase 2 clinical trials of oliceridine that were successful in showing potential differentiation of oliceridine from morphine. The Company expects top-line results to include measures of efficacy, safety, and tolerability of oliceridine compared to both placebo and morphine.***
>
> ***In addition, the Company announced that patient enrollment for the Phase 3 ATHENA multi-procedure safety study remains on track. The Company continues to anticipate filing a New Drug Application (NDA) for oliceridine with the U.S. Food & Drug Administration (FDA) in the second half of 2017.***
>
> **About the APOLLO-1 and APOLLO-2 Studies** [emphasis in original]
>
> Both APOLLO trials are Phase 3, multicenter, randomized, double-blind, placebo- and active-controlled studies of oliceridine for the treatment of moderate to severe acute pain. The APOLLO-1 study is evaluating pain for 48 hours following bunionectomy, and the APOLLO-2 study is evaluating pain for 24 hours following abdominoplasty. ***In each trial, patients were randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) device for the management of their post-operative pain.*** Each study enrolled approximately 375 patients, allocated equally across study arms. ***The primary objective in each study is to evaluate the analgesic efficacy of oliceridine compared to placebo. Secondary endpoints include comparisons of efficacy, safety, and tolerability of oliceridine to morphine.***

(Emphasis added unless noted).

106. The description Trevena provided concerning the design of the Phase 3 studies was misleading and contained material omissions in that the statement failed to disclose that the FDA had disagreed with Trevena's proposed dosing, the primary endpoint, and the methods by which Trevena planned to prove its secondary endpoints.

107. The statement that Trevena expected the study results to include "measures of . . . safety . . . of oliceridine compared to both placebo and morphine" was also materially false and misleading in that it failed to disclose that in November 2016, the FDA informed Trevena that it "did not agree with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine."

108. Furthermore, Trevena's statement that the "ATHENA multi-procedure safety study remains on track" was misleading and contained material omissions in that the statement failed to disclose that the FDA had explicitly instructed Trevena that the safety database must include at least 350 patients exposed to the highest intended dose for the longest expected duration of use. Trevena also failed to disclose that this requirement was due to the FDA's disagreement with Trevena's proposed dosing of 100 mg daily, given that Trevena had only studied maximum daily doses of 36.8 mg and did not have adequate non-clinical support for the proposed dosing. Indeed, an FDA Briefing Document would later reveal that during the review cycle, Trevena "modified the recommended maximum daily dose and dosing instructions . . . several times" including reducing the maximum daily dose "from 100 mg daily to 40 mg daily to try to address the adequacy of the safety database[.]" Even with the undisclosed modifications, the FDA Briefing Document shows that Trevena was never able satisfy the safety database requirements—instead the highest daily dose that had at least 350 patients exposed was only 27 mg, and the highest dose with the longest actual duration that had at least 350 patients was only

37.2 mg over a period of 35.5 hours, as described in ¶ 150, below. Not only was Trevena never "on track" to complete the safety study to the FDA's satisfaction, it was also covertly reducing the maximum daily dose and dosing instructions in the hopes of producing acceptable results.

109. On February 21, 2017, Trevena issued a press release entitled "Trevena Announces Positive Top-line Results from Two Phase 3 Pivotal Efficacy Studies of Intravenous Oliceridine in Moderate-to-Severe Acute Pain." In part, the press release stated:

> Trevena, Inc. (NASDAQ: TRVN) today announced positive top-line results from its Phase 3 APOLLO-1 and APOLLO-2 pivotal efficacy studies of oliceridine in moderate-to-severe acute pain following bunionectomy and abdominoplasty, respectively. In both studies, all dose regimens achieved their primary endpoint of statistically greater analgesic efficacy than placebo, as measured by responder rate. In addition, oliceridine showed dose-related trends of improvements vs. morphine on numerous measures of respiratory safety and gastrointestinal tolerability — both key unmet needs in acute pain management.
>
> "These data are exciting — they confirm earlier data, and show an improved safety and tolerability profile of oliceridine compared to morphine, with very similar results across the two studies," said Timothy Beard, M.D., FACS, Chair of Department of Surgery, Bend Memorial Clinic, Oregon.
>
> "We believe the data for all three dose regimens will support FDA approval of IV oliceridine with a broad indication of management of moderate-to-severe acute pain. These successful trials cap a development program that has shown consistent differentiation of oliceridine from morphine in multiple clinical trials," said Maxine Gowen, Ph.D., chief executive officer. "We look forward to submitting a new drug application with the goal of bringing this innovative product to patients."
>
> Both APOLLO trials were Phase 3, multicenter, randomized, double-blind, placebo- and active-controlled studies of oliceridine. The primary objective of each study was to evaluate the analgesic efficacy of oliceridine compared to placebo. Secondary endpoints included comparisons of efficacy, safety, and tolerability of oliceridine to morphine. Both studies included multiple measurements of nausea and vomiting, which occur in approximately 30% of postoperative patients and increase costs to hospitals, as well as multiple measures of respiratory safety, which can pose serious and costly risks to patient safety.
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> * * *
>
> **Oliceridine program update**

> The Company also announced that patient enrollment for the Phase 3 ATHENA multi-procedure safety study remains on track, with over 400 patients treated with oliceridine and no apparent off-target or unexpected adverse effects to date. In addition, a recently completed renal impairment study suggests that no dose adjustment will be required in renally impaired patients, and a metabolism study showed no evidence of active metabolites. These data distinguish oliceridine from conventional opioids like morphine and hydromorphone and support ease of administration for oliceridine — particularly in at-risk patients for whom safe opioid titration can be challenging. All additional clinical, non-clinical, and manufacturing activities remain on track to support an NDA submission in the fourth quarter of this year.

110. The results Trevena reported concerning the Phase 3 efficacy trials, that "[i]n both studies, all dose regimens achieved their primary endpoint of statistically greater analgesic efficacy than placebo, as measured by responder rate" was misleading and contained material omissions in that the statement failed to disclose that the FDA had disagreed with Trevena's proposed dosing and primary endpoint.

111. Trevena's statement that "oliceridine showed dose-related trends of improvements vs. morphine on numerous measures of respiratory safety and gastrointestinal tolerability" also was misleading and contained material omissions in that the statement failed to disclose that the FDA had disagreed with Trevena's proposed non-inferiority margin for comparing morphine to oliceridine and did not agree with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine.

112. Furthermore, defendant Gowen's statement that "We believe the data for all three dose regimens will support FDA approval of IV oliceridine with a broad indication" and that the "successful trials . . . ha[ve] shown consistent differentiation of oliceridine from morphine in multiple clinical trials" was misleading and contained material omissions because the statement failed to disclose that the FDA had disagreed with Trevena's proposed dosing, primary endpoint, an non-inferiority margin for comparing morphine to oliceridine.

113. The description of the Phase 3 studies including "multiple measures of respiratory safety" also was misleading and contained material omissions in that the statement failed to disclose that the FDA did not agree with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine.

114. Furthermore, Trevena's discussion of the Phase 3 study results was misleading and contained material omissions in that the statement failed to disclose that the FDA had instructed the Company to "submit amendments to modify all protocols for ongoing clinical trials" to include certain safety assessments, because Trevena's Phase 2 study saw "QTcF prolongation [which] exceeded the 10-ms regulatory threshold at clinically relevant exposures." Unbeknownst to investors, Trevena failed to implement the additional safety assessments, leading the FDA to conclude that "the limited ECG monitoring data [which the FDA had instructed Trevena to collect] in Phase 3 do not appear to be adequate to evaluate the QT effects of oliceridine" as described in ¶ 150, below.

115. Also, on February 21, 2017, defendants Gowen and Soergel held a conference call to discuss the top-line results for the Phase 3 efficacy studies. In addition to repeating the false and misleading statements described in ¶¶ 109-14, above, defendant Gowen acknowledged during the call that "[a] particular challenge was including morphine as a comparator in the trial, not the norm in our industry, and we took this step once again in order to demonstrate the benefit of this innovative next-generation opioid compared head to head to conventional opioids. . . . [W]e delivered two highly successful trials." Gowen's statement was misleading and contained material omissions in that it failed to disclose that the FDA did not agree with Trevena's proposed non-inferiority margin for comparing morphine to oliceridine and that the FDA had

informed Trevena that any comparative safety claims would have to be established in the setting of comparable efficacy between comparators to be considered for inclusion in labeling.

116. During the call, defendant Soergel also discussed Trevena's use of a responder analysis to assess the primary efficacy endpoint, explaining that Trevena "use[d] this analysis because it reflects the efficacy of the drug in the cleanest way." Soergel's statement was misleading and contained material omissions in that it failed to disclose that the FDA did not agree with Trevena's use of a responder analysis in its proposed primary endpoint.

117. Defendant Soergel also discussed the secondary endpoints, "including respiratory safety compared to morphine and non-inferiority on efficacy compared to morphine." Soergel's discussion was misleading and contained material omissions in that it failed to disclose that the FDA did not agree with Trevena's proposed non-inferiority margin for comparing morphine to oliceridine and did not agree with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine.

118. On March 8, 2017, Trevena issued a press release announcing its fourth quarter and fiscal year 2016 financial results. The press release stated in part:

> "The recent successful completion of the pivotal efficacy studies for OLINVO puts us in a strong position to bring this innovative analgesic to physicians and patients in need of a new option for managing moderate-to-severe acute pain in the hospital," said Maxine Gowen, Ph.D., chief executive officer. "We believe the data from these studies highlight the potential for OLINVO to reduce the burden of opioid-related adverse effects, particularly for those patients who are at elevated risk for serious consequences from post-operative nausea and vomiting or opioid-induced respiratory depression."
>
> **2016 and recent corporate highlights**
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> * * *
>
> - **Successful End-of-Phase 2 meeting with FDA.** In May 2016, the Company announced that it had reached general agreement with the FDA on key elements of the Phase 3 OLINVO program to support a New Drug Application (NDA), including that the APOLLO-1 and APOLLO-2

pivotal efficacy trials in bunionectomy and abdominoplasty included appropriate patient populations to support an indication for moderate-to-severe acute pain.

- **In February 2017, announced positive top-line results from two Phase 3 pivotal efficacy studies of OLINVO in moderate-to-severe acute pain**. OLINVO demonstrated fast onset and strong opioid efficacy in hard tissue and soft tissue pain models, supporting the Company's planned NDA submission and a potential indication for the management of moderate-to-severe acute pain. Numerous measures of respiratory safety and gastrointestinal tolerability all showed trends of meaningful improvements for OLINVO compared to a commonly used IV morphine regimen.

- **Initiated Phase 3 ATHENA open label safety study of OLINVO**. In January 2016, the Company announced the launch of the OLINVO Phase 3 clinical program with the enrollment of patients in the open label Phase 3 ATHENA study. This study is evaluating the safety and tolerability of OLINVO in patients with acute moderate-to-severe pain in a variety of surgical settings. As of February 15, 2017, more than 400 patients have been treated with OLINVO, with no apparent off-target or unexpected drug-related adverse effects to date. The Company remains on track to submit an NDA for OLINVO in the fourth quarter of 2017.

119. Trevena's description of its "successful" End-of-Phase 2 meeting with the FDA, in which it claimed to have reached general agreement with the FDA on "key elements" of the Phase 3 program was misleading and contained material omissions in that the statement failed to disclose the FDA's disagreement with the key elements of the Phase 3 program, including Trevena's proposed dosing, primary endpoint, non-inferiority margin for comparing morphine to oliceridine, and how Trevena would prove its secondary endpoints.

120. The overview of the "positive" top-line results from the Phase 3 efficacy trials, including that the studies demonstrated "strong opioid efficacy" to support the Company's planned NDA, as well as the claims of meaningful improvement in respiratory safety compared to morphine also were misleading and contained material omissions in that the statements failed to disclose that the FDA did not agree with Trevena's proposed primary endpoint and did not

agree with Trevena's proposal to evaluate oliceridine's respiratory safety as compared to morphine.

121. Furthermore, the statement that the ATHENA safety study "remains on track" was misleading and contained a material omission in that it failed to disclose that the FDA had set minimum criteria for the safety database due to concerns about Trevena's proposed dosing regimen. The statement also failed to disclose that Trevena was never "on track" to complete the study to the FDA's satisfaction, despite having modified the proposed maximum dosing and dosing instructions on multiple occasions in order to address the adequacy of the safety database, as described in ¶ 150, below.

122. Defendants Gowen and Soergel conducted a conference call on the same day. During the call, defendant Gowen discussed the results of the Phase 3 trials, stating in part:

> So, these data also emphasize the strong efficacy of OLINVO comparable to morphine, but also suggest that the OLINVO regimen using 0.35 milligram doses allowed patients to dose themselves to the best balance of efficacy and safety and tolerability.
>
> Another important feature of efficacy is the ability of the physician to use the drug as they are accustomed to using conventional opioids, adjusting the dose freely as they optimize therapy to the individual needs of each patient and this is the way physicians work with opioids and we have deliberately generated data using both PCA and bolus dosing over a broad range in our Phase 2 and 3 trials. Doing so clearly demonstrating the efficacy of OLINVO in comparison to morphine.
>
> * * *
>
> Let's turn now to the safety and tolerability of the product. First we've measured respiratory safety in multiple different ways across five clinical trials and in each case have shown the benefit of OLINVO compared to morphine. Here in our Phase 3 APOLLO trials our key secondary endpoint was respiratory safety burdens, which we measure as the product of the incidents of a respiratory safety event and its average duration.
>
> * * *
>
> This chart shows the frequency of respiratory safety events in the two trials and these are new data that we are showing you today and in this case we not only

> again see the clear trends but also statistical significance in the 0.35 milligram group in APOLLO-1. These data very consistent with our Phase 2 results in which this was our pre-specified endpoint. So we are consistently seeing a meaningful reduction in respiratory safety measures with the 0.35 meg regimen which in APOLLO-1 was about a 50% reduction, both statistically and highly clinically significant. And we also believe that this level of reduction will provide meaningful reductions in the cost of care as well.

123. Defendant Gowen's discussion of the positive efficacy and dosing data from the Phase 3 studies was misleading and contained material omissions in that her statement failed to disclose that the FDA did not agree with Trevena's proposed dosing or primary endpoint.

124. Likewise, Defendant Gowen's discussion of positive respiratory safety data from the Phase 3 studies omitted the material fact that the FDA did not agree with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine.

125. On May 4, 2017, Trevena issued a press release announcing its first quarter 2017 financial results. The press release stated in part:

> "This quarter marked a key milestone for our OLINVO program, with the delivery of robust data that we believe will support our new drug application and demonstrates the potential value of OLINVO for the management of moderate-to-severe acute pain in the hospital," said Maxine Gowen, Ph.D., chief executive officer. "There remains a critical unmet need for patients who require IV opioids to manage pain but are at risk for poor outcomes from opioid-related adverse effects. Our successful Phase 3 data showed not only significant efficacy of OLINVO versus placebo to support approval, but also showed the potential for fewer gastrointestinal and respiratory adverse effects while providing comparable pain relief to a commonly used morphine regimen."
>
> **First quarter and recent corporate highlights**
>
> - **Announced positive top-line results from two Phase 3 pivotal efficacy studies of OLINVOTM (oliceridine injection) for moderate-to-severe pain.** In February, the Company announced positive data from the APOLLO-1 and APOLLO-2 studies of OLINVO in moderate-to severe-acute pain following hard tissue and soft tissue surgeries, respectively. OLINVO demonstrated significant analgesic efficacy compared to placebo in both studies for all three tested dosing regimens. Consistent with Phase 2b results, a 0.35 mg dose regimen provided comparable pain relief to a common IV morphine regimen and showed potential to reduce opioid-

related adverse effects on multiple measures of respiratory safety and gastrointestinal tolerability.

- **OLINVO program remains on track for a new drug application (NDA) submission in 4Q 2017.** As of March 31, 2017, approximately 600 patients have been treated with OLINVO in the ongoing open-label, multi-procedure ATHENA safety study. In addition, the Company has successfully completed a chemistry, manufacturing, and controls Type B pre-NDA meeting with the U.S. Food and Drug Administration (FDA), and all pre-NDA activities remain on track to support an NDA submission to the FDA in the fourth quarter of 2017.

126. The overview of the "positive" top-line results from the Phase 3 efficacy trials, including that the studies demonstrated "significant analgesic efficacy," the positive results of the dosing regimen, as well as the claims of meaningful improvement in respiratory safety compared to morphine was misleading and contained material omissions in that the statements failed to disclose that the FDA did not agree with Trevena's proposed primary endpoint, did not agree with Trevena's proposed dosing, and did not agree with Trevena's proposal to evaluate oliceridine's respiratory safety as compared to morphine.

127. The description of the ATHENA safety study also was misleading and omitted the material fact that the FDA had set minimum criteria for the safety database due to concerns about Trevena's proposed dosing regimen. The statement also failed to disclose that Trevena had unsuccessfully modified the proposed maximum dosing and dosing instructions on multiple occasions in order to address the adequacy of the safety database, as described in ¶ 150, below.

128. On May 5, 2017, Trevena met privately with the FDA concerning the design of its Phase 3 clinical trials. According to the FDA's later-published description of those communications:

May 5, 2017 – Advice on Integrated Statistical Analysis Plan (ISAP) for the Integrated Summary of Safety

- Agency agreed with the proposed pooling for the ISAP, the planned subgroups for analysis of intrinsic and extrinsic factors, and planned summarization of adverse events.

- FDA reiterated the concerns noted at the November 8, 2016, teleconference regarding the assessment of respiratory safety. It was noted that the RSE as described in the ISS statistical plan would be considered exploratory and would not be acceptable for a proposed labeling claim.

129. On July 20, 2017, Trevena announced that defendant Soergel, its Chief Medical Officer, was resigning.

130. Also, on July 20, 2017, defendants Gowen and Soergel presented the results of the ATHENA safety study at their 2017 Analyst Day. During the presentation, defendant Gowen discussed the safety study, stating: "And of course, we now have a complete safety database to support the NDA file." During the Q&A portion of the presentation, defendants Gowen and Soergel answered a question from Antonio Eduardo Arce, an analyst at H.C. Wainwright & Co. LLC as set forth below:

> Q. And then Maxine, just 1 final question related to commercial. It's a bit early yet – you haven't even submitted – but ***wondering your thoughts on how you see ultimately the labeled indication coming out? Do you see any kinds of particular restrictions?***
>
> A. [Gowen] No. I don't think we anticipate restrictions. ***We anticipate a broad indication statement because we followed the guidance to get that. And we're hoping that we've now generated more than enough data to get broad dosing administration guidance.*** So restrictions, I can't think of any that we've identified at this point.
>
> A. [Soergel] So ***our goal has been to have a label that looks like other opioids from the perspective of sort of lack of a maximum dose, huge flexibility of administration and then language around titration. So take care of the patient's pain with as much drug as you need to and balance their side effects***, in summary as a (inaudible). So that's been our goal and that's been what we've guided the development plan towards.

(Emphasis added).

131. Defendant Gowen and Soergel's above statements were misleading and contained material omissions in that they failed to disclose that the FDA informed Trevena that it did not agree with the proposed dosing of up to 100 mg daily for the Phase 3 program because Trevena had previously only studied maximum daily doses of 36.8 mg, and informed Trevena that the safety database must include at least 350 patients exposed to the highest intended dose for the longest expected duration of use. As revealed in the FDA Briefing Document on October 9, 2018, Trevena's safety database failed to meet the FDA's minimum requirements despite lowering the proposed maximum daily dose and dosing instructions on multiple occasions in an attempt to address the adequacy of the safety database. Specifically, the highest dose that had at least 350 patients exposed during the first 24 hours was only 27 mg, and the highest dose with the longest actual duration that had at least 350 patients exposed was only 37.2 mg over 35.5 hours, as described in ¶ 150, below. By the time of the July 20, 2017 statements, defendants Gowen and Soergel knew, or recklessly disregarded, that the safety database did not meet the FDA's minimum requirements. Given the FDA's explicit instructions for the safety database, defendants had no reasonable basis to believe that Trevena had a "complete safety database" that would support "broad dosing administration guidance" with "a lack of a maximum dose" and "huge flexibility of administration." Indeed, after receiving notification that the FDA had formally rejected Trevena's application, Trevena acknowledged in a press release on November 2, 2018 that the FDA stated that the "submitted safety database is not of adequate size for the proposed dosing." In other words, the FDA's position was not the result of a difference of opinion in interpreting scientific data. Rather, it was the result of Trevena's blatant failure to follow the FDA's explicit instructions.

132. On August 3, 2017, Trevena issued a press release announcing its second quarter 2017 financial results. The press release stated in part:

> "The second quarter saw continued progress towards our goal of delivering an innovative new option for patients who are at risk of adverse events associated with IV opioids like morphine," said Maxine Gowen, Ph.D., chief executive officer. "We have now completed our Phase 3 clinical development for OLINVO and successfully completed our pre-NDA meetings with the FDA. In addition, we have refined our commercial strategy to lay the groundwork for a successful commercial launch. With the comparative data from our successful APOLLO pivotal efficacy studies, as well as data and investigator observations from more real-word use in the ATHENA open label study, we believe the value of OLINVO will resonate with potential prescribers who want to improve the care of hospital patients suffering severe pain."
>
> **Second quarter and recent corporate highlights**
>
> - **OLINVO™ (oliceridine injection) program remains on track for a new drug application (NDA) submission in September/October 2017.** In July 2017, the Company announced that enrollment in the ATHENA open-label safety study was complete to support the NDA file, with 772 patients treated with OLINVO across more than 40 sites. In addition, the Company successfully completed a chemistry, manufacturing, and controls (CMC) Type B pre-NDA meeting and a preclinical and clinical Type B pre-NDA meeting with the U.S. Food and Drug Administration (FDA). All pre-NDA activities remain on track to support an NDA submission to the FDA in September/October of 2017.

(Underline emphasis added).

133. The description of the "comparative data from our successful APOLLO pivotal efficacy studies" was misleading and contained material omissions in that the statement failed to disclose that the FDA did not agree with Trevena's proposed primary endpoint, non-inferiority margin for comparing morphine to oliceridine. The statement also omitted the material fact that the FDA disagreed with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine—a concern that was reiterated to Trevena in May 2017.

134. The statement that the "ATHENA open-label safety study was complete to support the NDA file" also was misleading and contained material omissions in that it failed to

disclose that Trevena had modified the proposed maximum daily dosing and dosing instructions on multiple occasions in order to address the adequacy of the safety database—which required at least 350 patients exposed to the highest intended dose for the longest expected duration of use—and that Trevena was never able to meet this FDA-imposed requirement. *See* ¶¶ 74, 79, 150, herein.

135. On November 7, 2017, Trevena issued a press release announcing its third quarter 2017 financial results. The press release stated in part:

> "The recent submission of the OLINVO NDA capped a transformative period for our Company," said Maxine Gowen, Ph.D., chief executive officer. "We are now focused on preparing for the approval and commercialization of OLINVO, while continuing to advance our development pipeline following our recent strategic decision to halt our discovery research efforts. To this end, new results continue to highlight the potential value of OLINVO for patients in a real world setting who require IV opioids but are at risk of opioid-related adverse events. Positive interim Phase 1 data for TRV250 bode well for future clinical development of this exciting potential migraine therapy."
>
> **Third quarter and recent corporate highlights**
>
> - **OLINVO New Drug Application submitted.** The Company recently submitted its New Drug Application (NDA) for OLINVO to the U.S. Food and Drug Administration (FDA). OLINVO is the first G protein biased ligand of the mu opioid receptor, a new class of opioid receptor modulator, and the first pain program to receive Breakthrough Therapy designation from the FDA. The submission includes data showing that intravenous OLINVO demonstrated analgesic efficacy in all three dosing regimens tested in the two Phase 3 APOLLO pivotal efficacy studies. These trials were designed to support an indication for the management of moderate-to-severe acute pain in adult patients for whom an intravenous opioid is warranted. The filing also includes safety and tolerability data for over 1,100 patients administered OLINVO across Phase 2 and Phase 3 studies, including the ATHENA open label safety study. Additional pharmacokinetic data, clinical pharmacology data, and results from five randomized controlled trials with head to head comparisons to morphine, support potential differentiation of OLINVO.
>
> - **New data from Phase 3 ATHENA open label safety study.** In July, the Company announced top-line results from the first 418 patients administered OLINVO to manage medical or postoperative pain in the ATHENA study, which was designed to model real-world use including

> multimodal analgesia regimens incorporating OLINVO. Data for all 768 patients administered OLINVO are now final, and highlight the effectiveness and utility of OLINVO in treating patients who require an IV opioid to manage pain.

(Underline emphasis added).

136. The description Trevena provided of its NDA submission concerning efficacy, dosing, and secondary endpoints was misleading and contained material omissions in that the statement failed to disclose that the FDA disagreed with Trevena's proposed dosing, primary endpoint, and non-inferiority margin for comparing morphine to oliceridine—on which the ability to secure inclusion of secondary endpoints on a potential label depended. The statement also omitted the material fact that the FDA disagreed with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine—a concern that was reiterated to Trevena in May 2017.

137. Trevena's statement that the data for the ATHENA safety study was now complete was misleading and contained material omissions in that it failed to disclose that Trevena had failed meet the FDA's requirement of providing a safety database that included at least 350 patients exposed to the highest intended dose for the longest expected duration of use, despite modifying the proposed maximum daily dose and dosing instructions on multiple occasions in order to address the adequacy of the safety database. *See* ¶¶ 74, 79, 150, herein.

138. On March 7, 2018, Trevena issued a press release announcing its fourth quarter and fiscal year 2017 financial results. The press release stated in part:

> "2017 marked important progress for Trevena as we completed our Phase 3 program and NDA submission for OLINVO and prepared to support commercial launch," said Maxine Gowen, Ph.D., chief executive officer. "We look forward to potential approval of OLINVO later this year, as well as advancement of our earlier R&D programs. We remain committed to bringing patients innovative medicines for safer and more successful pain management."
>
> **2017 and recent corporate highlights**

> **New Drug Application (NDA) for OLINVO submitted and accepted.** In January 2018, the Company announced that the FDA has accepted the Company's NDA for OLINVO. OLINVO is an investigational product for the management of moderate to severe acute pain. It is the first G protein biased ligand of the mu receptor designed to provide IV opioid pain relief with fewer associated adverse effects. The FDA has informed the Company that it intends to convene an advisory committee meeting to discuss the OLINVO NDA ahead of the Prescription Drug User Fee Act (PDUFA) review date of November 2, 2018. If approved, the Company expects commercial launch of OLINVO in the first quarter of 2019 following DEA scheduling.
>
> **Announced top line data from the successful Phase 3 open label ATHENA safety study.** In November, the Company announced top-line results from 768 patients administered OLINVO to manage medical or postoperative pain in the ATHENA study, which was designed to model real-world use including multimodal analgesia regimens incorporating OLINVO. Data highlight the potential effectiveness and utility of OLINVO in treating patients who require an IV opioid to manage acute pain. Patients at elevated risk of opioid-related adverse events were well represented in the study; more than 30% of patients were 65 years or older, and more than 50% of patients were obese, with body mass index (BMI) >30 kg/m2. Only 4% of patients discontinued for lack of efficacy, and 2% of patients discontinued for adverse events. Adverse event rates associated with OLINVO administered by patient controlled analgesia (PCA) and as-needed clinician-administered bolus dosing were similar, supporting potential use of OLINVO in both administration paradigms.

(Underline emphasis added).

139. The statement concerning the completion of the Phase 3 program and NDA submission was misleading and contained material omissions in that the statement failed to disclose that the FDA disagreed with Trevena's proposed dosing, primary endpoint, and non-inferiority margin for comparing morphine to oliceridine—on which the ability to secure inclusion of secondary endpoints on a potential label depended. The statement also omitted the material fact that the FDA disagreed with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine—a concern that was reiterated to Trevena in May 2017. Defendant Gowen's statement that "[w]e look forward to potential approval of OLINVO later this year" was also materially false and misleading because the foregoing omissions concealed the fact that FDA approval for oliceridine was unlikely.

140. The description of the ATHENA safety study also was misleading and contained material omissions in that it failed to disclose that Trevena had failed meet the FDA's requirement of providing a safety database that included at least 350 patients exposed to the highest intended dose for the longest expected duration of use, despite modifying the proposed maximum daily dose and dosing instructions on multiple occasions in order to address the adequacy of the safety database. *See* ¶¶ 74, 79, 150, herein.

141. On April 6, 2018, Trevena issued a press release announcing that defendant Gowen would be retiring from the Company effective October 1, 2018.

142. On May 3, 2018, Trevena issued a press release announcing first quarter 2018 financial results. The press release stated in part:

> "In 2018, we have made important progress in Trevena's evolution," said Maxine Gowen, Ph.D., president and chief executive officer. . . . We continue to have an ongoing productive dialogue with the FDA as they review our oliceridine NDA, and look forward to an advisory committee meeting later this year and potential approval in November."
>
> **First quarter and recent corporate highlights**
>
> **New Drug Application (NDA) for oliceridine submitted and accepted**. In January 2018, the Company announced that the FDA has accepted the Company's NDA for oliceridine, an investigational product for the management of moderate to severe acute pain. Oliceridine is the first G protein biased ligand of the mu receptor, and was designed to provide IV opioid pain relief with fewer associated adverse effects. The FDA has informed the Company that it intends to convene an advisory committee meeting to discuss the oliceridine NDA ahead of the Prescription Drug User Fee Act (PDUFA) review date of November 2, 2018. If approved, the Company expects commercial launch of oliceridine in the first quarter of 2019, following DEA scheduling.

(Underline emphasis added).

143. The positive description of Trevena's dialogue with the FDA and that the Company was "look[ing] forward to an advisory committee meeting later this year and potential approval in November" was misleading and contained material omissions in that the statement

failed to disclose that the FDA disagreed with Trevena's proposed dosing, primary endpoint, and non-inferiority margin for comparing morphine to oliceridine—on which the ability to secure inclusion of secondary endpoints on a potential label depended. The statement also omitted the material fact that the FDA disagreed with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine—a concern that was reiterated to Trevena in May 2017. The omitted information concealed the fact that FDA approval for oliceridine was unlikely.

144. On June 15, 2018, Trevena announced that it had entered into a Sales Agreement with Cowen and Company LLC ("Cowen") pursuant to which it would issue to Cowen and Cowen would sell up to $50 million of Trevena common stock at market prices. Trevena filed a prospectus with the SEC in connection with this anticipated offering that expressly incorporated by reference the Company's 2017 Form 10-K and its first quarter 2018 Form 10-Q, among other filings the Company had made with the SEC. The prospectus also expressly incorporated by reference all of the filings Trevena made with the SEC until the offering was complete.

145. On August 2, 2018, Trevena issued a press release announcing its second quarter 2018 financial results. The press release stated in part:

> "The second quarter saw important progress towards Trevena's long-term success," said Maxine Gowen, Ph.D., President and Chief Executive Officer. "We remain confident that the oliceridine NDA remains on track for an FDA decision by the November 2, 2018 PDUFA date, and we look forward to discussing the oliceridine data at an Advisory Committee meeting, likely in October. . . ."
>
> **Second quarter and recent corporate highlights**
>
> **Prescription Drug User Fee Act (PDUFA) date for oliceridine: November 2, 2018.** Oliceridine is an investigational product under FDA review for the management of moderate to severe acute pain where parenteral opioid analgesia is warranted and was designed to provide the pain relief of IV opioids with fewer associated adverse effects. The FDA has informed the Company that it intends to convene an advisory committee meeting, likely in October, to discuss the oliceridine NDA. If oliceridine is approved by the FDA, and following DEA

> scheduling, the Company expects the commercial launch of oliceridine in the first half of 2019.

(Underline emphasis added).

146. Trevena's statement concerning its NDA submission was misleading and contained material omissions in that the statement failed to disclose that the FDA disagreed with Trevena's proposed dosing, primary endpoint, and non-inferiority margin for comparing morphine to oliceridine—on which the ability to secure inclusion of secondary endpoints on a potential label depended. The statement also omitted the material fact that the FDA disagreed with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine—a concern that was reiterated to Trevena in May 2017. The statement also failed to disclose that Trevena had failed meet the FDA's requirement of providing a safety database that included at least 350 patients exposed to the highest intended dose for the longest expected duration of use, despite modifying the proposed maximum daily dose and dosing instructions on multiple occasions in order to address the adequacy of the safety database. *See* ¶¶ 74, 79, 150, herein. The omitted information concealed the fact that FDA approval for oliceridine was unlikely.

D. The Truth Is Revealed

147. Trevena's fraud was revealed to the market on October 9, 2018. On that day, as is customary, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee publicly issued its FDA Briefing Document in advance of its previously scheduled October 11, 2018 meeting to vote on its recommendation concerning the FDA's approval of oliceridine. This document revealed to the public for the first time the private interactions between the FDA and Trevena described herein.

148. The FDA Briefing Document made clear that the FDA's previously issued concerns were not heeded by Trevena. The market immediately understood that the Advisory Committee was not recommending the approval of oliceridine.

149. Specifically, the FDA Briefing Document stated:

> *Efficacy*: In FDA's analysis of efficacy for Study 3001, all three doses of oliceridine (0.1 mg, 0.35 mg, and 0.5 mg) demonstrated a statistically greater reduction in pain intensity than placebo. However, morphine demonstrated a greater reduction in pain intensity than all three doses of oliceridine that was also statistically significant. In FDA's analysis for Study 3002, two of the three doses of oliceridine (0.35 mg and 0.5 mg) demonstrated a statistically greater reduction in pain intensity than placebo, but the 0.1 mg dose did not. In Study 3002, morphine demonstrated a greater reduction in pain intensity relief than two of the doses of oliceridine (0.1 mg and 0.35 mg) that was statistically significant. The reduction in pain intensity by morphine was not greater than that of the highest oliceridine dose (0.5 mg). Currently, Trevena is only seeking approval of the 0.1 mg and 0.35 mg doses.
>
> A secondary objective of the studies was to demonstrate the superiority of oliceridine to morphine in terms of respiratory safety burden. ***FDA did not agree with Trevena's proposed endpoint due to concerns with its clinical meaningfulness***. Further, when evaluating this endpoint in both studies, none of the oliceridine treatment arms demonstrated a significant reduction in the expected cumulative duration of respiratory safety events compared to morphine. ***Further, any numeric trends in terms of respiratory safety must be considered in the context of the observed efficacy. A conclusion of benefit in a dose-related safety outcome cannot be made without a demonstration of similar efficacy***.
>
> *Safety*: Opioids are typically administered as needed (PRN) for acute pain. In the Phase 3 studies, the oliceridine dosing regimen included a clinician-administered loading dose, patient-delivered PRN dosing via patient-controlled analgesia (PCA) pump, clinician-administered PRN supplemental dosing, or some combination of these. ***This complex PRN dosing resulted in a wide range of patient exposures and added complexity to the safety analyses.*** Given the variability in doses administered, the Applicant and Agency analyzed safety in a variety of ways, including by randomized treatment regimen and by cumulative oliceridine exposure.
>
> The agency analysis of the safety of oliceridine in the Phase 3, double-blind studies focused on comparisons of the randomized oliceridine treatment arms by study, so that the safety results could be considered in the context of the efficacy of the evaluated doses. Many adverse events in the clinical program were consistent with opioid-related adverse events, including respiratory depression and hypoxia, and nausea and vomiting. When evaluating the controlled Phase 3

> data by randomized treatment group, many of the adverse events were dose-related, including respiratory effects. While there were trends showing a decreased percentage of respiratory events as defined by the applicant with oliceridine than morphine for some parameters, this was not consistent across all parameters. ***Notable safety issues in the clinical program included hepatic adverse events and QT prolongation. An additional consideration is whether the safety database is adequate to support the proposed dosing.***

(Emphasis added).

150. The FDA Briefing Document also contained a plethora of information demonstrating that Trevena failed to heed the FDA's advice throughout the review process. These issues were concealed from investors, and the market, and contributed significantly to the ultimate vote against approval for oliceridine. The table below lists the issues raised by the FDA during the review process in the left column and summarizes the impact of Trevena's failure to address those issues in the right column:

Regulatory Interaction	Discussion in Briefing Document
March 3, 2016 – Advice regarding ECGs – Written Advice FDA issued written advice to the Applicant because QTcF prolongation exceeded the 10-ms regulatory threshold at clinically relevant exposures. The Applicant was instructed to submit amendments to modify all protocols for ongoing clinical trials to include the following safety assessments, and incorporate them into any future clinical trials: 1. Conduct safety ECG monitoring at baseline, following the first dose, and periodically thereafter. The timing of ECGs will need to reflect the delayed response relative to time of peak concentrations that was observed in the thorough QT study. Include additional ECG monitoring until ECGs return to baseline in patients discontinued from the trial or requiring dose reduction due	Because the QTcF prolongation exceeded the 10-ms regulatory threshold at clinically relevant exposures, **FDA sent an advice letter/information request to the Applicant** on 3/3/16, indicating that the Applicant should incorporate safety ECG monitoring at baseline, following the first dose, and periodically thereafter. **It was noted that the timing of the ECGs will need to reflect** that delayed response relative to peak concentrations that was observed in the thorough QT study. In the Applicant's Phase 3 studies, **only limited ECG monitoring was obtained** in patients (1, 24, and 48-hours post-loading doses for study 3001 and 1 and 24 hours for Study 3002). Given that QTcF prolongation associated with oliceridine is delayed and oliceridine is administered as needed with a wide range of doses up to a proposed maximum daily dose of initially 100mg and then decreased by the Applicant to 40mg, the data from a single dose tQT study and **the**

to QTc interval prolongation. 2. Periodic monitoring of electrolytes (subjects already participating in the study with serum potassium, magnesium, or calcium levels outside of the central laboratory's reference range should be carefully monitored and brought to normal values). 3. Propose dose-modification and discontinuation criteria in subjects with posttreatment QTc > 500 ms or post-baseline increases > 60 ms.	**limited ECG monitoring data obtained in Phase 3 do not appear to be adequate to evaluate the QT effects of oliceridine.** "While the Applicant states that there were no significant QTcF changes noted in the clinical studies, studies 3001, 3002, or 3003 were not designed to characterize the QT prolonging effect of oliceridine" and "Further, it is worth noting that the ECG monitoring was sparse (baseline, 1 hour, and every 24 hours) and the absence of observed QTc prolongation **is therefore not particularly reassuring.**" The concerns regarding QT prolongation were noted by the Agency at the Midcycle Communication with the Applicant on May 21, 2018. In follow-up, the Applicant proposed simulations of the QTcF under various dosing scenarios a re-analysis of the tQT study using different ECG biomarkers. The Agency responded that since mechanism of the delayed QTcF prolongation is unknown, **it is not appropriate to extrapolate information** from single 3 mg and 6 mg does to the proposed multiple dose scenarios (up to 3 mg every 1 hour).

March 29, 2016 (meeting minutes April 28, 2016) – End-of-Phase 2 Meeting FDA did not agree with the proposed dosing in the Phase 3 studies. The Sponsor proposed dosing up to 100 mg daily (including a 0.75 mg every 1 hour as needed clinician administered dose), but had only studied maximum daily doses of 36.8 mg. Further, the Sponsor did not have adequate non-clinical support for the proposed doses. FDA noted that the safety database must include at least 350 patients exposed to the highest intended dose for the longest expected duration of use. It was noted that the safety database requirements might change if safety signals arise during development that require further evaluation.	A **significant consideration during the review cycle was whether the size of the safety database was adequate**. Prior to submission of the NDA, **the Applicant was told at the End-of-Phase 2 meeting and the pre-NDA meeting that they would need at least 350 patients exposed to the highest intended doses for the longest expected duration of use.** Figure 15 shows the frequency of cumulative exposure to oliceridine for the first 24 hours for the pooled Phase 2 and Phase 3 studies. **The data are skewed**, with most patients receiving doses less than 75 mg. The Applicant's initially proposed labeling included a maximum daily dose of 100 mg without a limit on duration of use. The Applicant was asked to clarify the highest does that has at least 350 patients exposed for 24 hours and the highest does that has at least 350 patients exposed for the longest actual duration of use. The highest dose that has at least 350 patients exposed during the first 24 hours of dosing was 27 mg of oliceridine. The highest dose with the longest actual duration that has at least 350 patients exposed was 37.2 mg of oliceridine over an actual duration of at least 35.5 hours. During the review cycle, the **Applicant reduced the proposed maximum daily dose** from 100 mg daily to 40 mg daily **to try to address the adequacy of the safety database and nonclinical concerns regarding the adequacy to qualify major metabolites**. During the review cycle, **Trevena modified the recommended maximum daily dose and dosing instruction in the proposed label several times**.

March 29, 2016 (meeting minutes April 28, 2016) – End-of-Phase 2 Meeting FDA did not agree with the proposed primary endpoint, as it was unclear how a 30% improvement from baseline based on SPID correlates to an improvement in pain intensity scores on the NRS in the proposed setting of acute postoperative pain and if that change is clinically relevant. The Applicant provided details of a proposed approach to missing data. This approach included replacing pain scores in the window determined dosing interval described in the label of the rescue medication following rescue with the pain score recorded immediately prior to rescue	This **endpoint is novel and has never been the basis for approval for any drugs in this class**. **Consequently, sensitivity analyses were also performed directly on the SPID scores** which are typically used as the primary efficacy endpoint in this setting. Since the Applicant's primary efficacy analyses was based on a novel responder definition, i.e. 30% improvement in SPIDs, FDA conducted an analysis using SPIDs rather than the proposed responder definition. **FDA disagreed with how information regarding use of rescue medication was used in the Applicant's derivation of SPIDs.** Carrying forward the final pre-rescue score from the first use of rescue until the end of the observation period ignores the fact that the effect of the rescue medication will expire, and the fact that patient's pain scores would continue to improve throughout the study even in the placebo arm. **The consequence is that it harshly penalizes patients who used rescue medication. FDA used an alternative analysis which carries forward the pre-rescue scores for the dosing interval of the rescue medication, which is commonly used in studies of analgesics in the post-surgical setting, and considered the most clinically relevant**.
March 29, 2016 (meeting minutes April 28, 2016) – End-of-Phase 2 Meeting FDA did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine.	Secondary Efficacy Analysis: Non-inferiority assessment of oliceridine to morphine: **While this is critical in light of the application's objective of demonstrating a reduction in the respiratory safety burden for oliceridine compared to morphine, there was no agreement on the Applicant's definition of the non-inferiority criteria**.

March 29, 2016 (meeting minutes April 28, 2016) – End-of-Phase 2 Meeting Any comparative safety claims must be replicated, adequately justified for clinical relevance, and established in the setting of comparable efficacy between comparators to be considered for inclusion in labeling	A secondary objective of the studies was to demonstrate the superiority of oliceridine to morphine in terms of respiratory safety burden. **FDA did not agree with Trevena's proposed endpoint due to concerns with its clinical meaningfulness**. Further, when evaluating this endpoint in both studies**, none of the oliceridine treatment arms demonstrated a significant reduction** in the expected cumulative duration of respiratory safety events **compared to morphine**. Further, any numeric trends in terms of respiratory safety events must be considered in the context of the observed efficacy. A **conclusion of benefit in a dose-related safety outcome cannot be made without a demonstration of similar efficacy**.
November 8, 2016 (meeting minutes 12/19/16) – Type C teleconference FDA did not agree with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine because the definition of Respiratory Safety Events (RSEs) was not clearly defined and the determination of the presence of an RSE relied largely on clinical acumen. Even though the parameters proposed in the evaluation of an RSE (respiratory rate, oxygen saturation, and MRPSS somnolence/ sedation scores) are well accepted criteria used for the assessment of patients at risk for experiencing an RSE, it is unclear that a small change in these parameters is of clinical significance. Trevena was told to specify a clinically meaningful definition of an RSE, such as patients who require a clinical intervention after meeting a specific criterion (e.g., naloxone administration and/or oxygen administration with a reduction in oxygen saturation). Further, FDA did not agree with inclusion of sedation and somnolence in the RSE definition. FDA stated that the statistical model proposed to evaluate the respiratory safety of oliceridine incorporates both the population prevalence of RSEs and the population conditional mean	**The key secondary safety endpoint** was the respiratory safety burden, as measured by the occurrence and duration of respiratory safety events (RSEs) within patients. The Applicant also recorded information on the cumulative duration of supplemental oxygen administration and the cumulative duration of recovery from RSE. A RSE was defined as a clinically relevant worsening of respiratory status. The respiratory safety burden safety/tolerability endpoint incorporated both the prevalence of RSEs and the expected duration of time that a patient would experience an RSE if one occurred, into a single composite measure. This endpoint was intended to correspond to the total amount of time a patient from the population should have expected to experience an RSE and represents the respiratory safety burden for a given treatment regimen. **However, there is no precedent for use of this endpoint in a clinical study and the FDA did not agree that this was a clinically interpretable endpoint for the evaluation of a potential respiratory claim. During development, FDA informed the Applicant that their definition of RSE was not clearly defined and relied largely on clinical acumen.**

cumulative duration of RSEs to describe respiratory safety burden (RSB). Based on this model, a small change in event duration could result in a statistically significant result without clinical significance. In addition, the RSB endpoint is difficult to interpret and apply directly to clinical practice. Trevena was asked to analyze and report event duration separately from the event prevalence	Based on oliceridine's mechanism of action, the Applicant hypothesized that it may be associated with less respiratory depression than other opioids. The Applicant pre-specified a safety endpoint referred to as respiratory safety burden to assess the respiratory safety of oliceridine compared to morphine and placebo. However, FDA did not agree with the Applicant's proposal to evaluate respiratory safety based on respiratory safety events (RSEs) or respiratory safety burden as discussed in Section 1.1. **A significant Agency concern was whether the Applicant's definition of an RSE or a small change in RSE was clinically meaningful**.
May 5, 2017 – Advice on Integrated Statistical Analysis Plan (ISAP) for the Integrated Summary of Safety Agency agreed with the proposed pooling for the ISAP, the planned subgroups for analysis of intrinsic and extrinsic factors, and planned summarization of adverse events FDA reiterated the concerns noted at the November 8, 2016, teleconference regarding the assessment of respiratory safety. It was noted that the RSE as described in the ISS statistical plan would be considered exploratory and would not be acceptable for a proposed labeling claim	Of note, the Applicant performed study 1003, which assessed ventilatory response to hypercapnia and cold pain testing in healthy volunteers. **The Agency considers this study to be a proof-of-concept study that is not adequate to provide regulatory support for a respiratory safety claim**.

151. Upon publication of this news, the price of Trevena common stock plummeted. Shares closed on October 9, 2018 down 64% from the prior trading day with unusually high volume—more than 40 million shares traded hands.

152. Investors knew the Advisory Committee's recommendation would be important to the FDA: In an article published August 16, 2016 on the website www.eyeonfda.com, titled "AdComm Recommendations – How Often FDA Does Not Follow Them?," attorney and pharmaceutical industry consultant Mark Senak analyzed every advisory committee meeting held from 2011 through 2016. Of the 231 meetings, 145 were held to consider a treatment candidate for approval—with a decision reached in 136 of those 145 meetings. Of the 136 meetings, the

FDA went against the recommendation of the Advisory Committee on just 13 occasions, or less than 10% of the time. In other words, the FDA nearly always follows the recommendation of the Advisory Committee.

153. On October 11, 2018, Trevena filed with the SEC a Current Report on Form 8-K, pursuant to Regulation F-D, concerning some of the Company's prior communications with the FDA about its Phase 3 clinical trial design for oliceridine:

> Trevena, Inc. (the "Company" or the "Sponsor") is providing the following information to clarify and further expand upon the interactions between Trevena and the U.S. Food and Drug Administration ("FDA") with respect to the primary endpoint for the two pivotal Phase 3 studies, APOLLO-1 and APOLLO-2, conducted by the Company with respect to oliceridine.
>
> Prior to the Company's End-of-Phase 2 meeting, the Division of Anesthesia, Analgesia, and Addiction Products (the "Division"), Center for Drug Evaluation and Research of FDA indicated to the Company that it did not agree with the proposed primary efficacy endpoint for the APOLLO-1 and APOLLO-2 studies. Following this, the Company submitted additional analyses to, and had further discussions with, the Division. In the meeting minutes dated April 28, 2016 from the End-of-Phase 2 meeting between the Division and the Company, the Division indicated the following to the Company:
>
> > "Regarding the relevance of the proposed primary endpoint, the Sponsor plans to include multiple secondary endpoints in their analyses to reflect appropriate endpoints of clinical importance. They have tried patient global assessments, but these have limitations in the acute setting. The Division stated that while a 30% improvement in summed pain intensity difference (SPID) is acceptable statistically, the clinical relevance of a 30% improvement in this setting using this measure is not clear. Interpretability of SPIDs can be challenging because the value is dependent on the formula for calculating the SPID and has no obvious meaning. Further, the SPID may be different for the two treatment groups, but the difference can reflect only an early or late effect. The Division stated that a 30% decrease in pain has typically been used as a marker to determine a clinically-meaningful difference in chronic pain settings. **The Division has no objection to use of a responder rate as an endpoint, however, the Sponsor must incorporate those patients who discontinue into the analysis as non-responders.**" (emphasis added)

(Underline emphasis added, bold emphasis in original).

154. The Company announced later in the day on October 11, 2018, that the Analgesic Drug Products Advisory Committee of the FDA voted "8 against, and 7 in favor of, the approval of oliceridine for the management of moderate to severe acute pain in adult patients for whom an intravenous (IV) opioid is warranted." The Company acknowledged that while "[t]he FDA [was] not bound by the Advisory Committee's recommendations," it "takes its advice into consideration when making its decision."

155. Trevena stock was halted throughout the day on October 11, 2018, pending news. When trading commenced on October 12, 2018, Trevena stock dropped another 7%, closing below $1 per share, on high volume.

156. On November 2, 2018, Trevena disclosed that the FDA had formally rejected its NDA for oliceridine, stating in a Complete Response Letter that, among other things, Trevena's safety database was not adequate for the proposed dosing and that additional clinical data on QT prolongation was required. While Trevena did not disclose the full contents of the Complete Response Letter, which remains confidential, the two reasons for rejection that Trevena did disclose were raised by the FDA prior to the start of the Phase 3 trials.

VIII. DAMAGES TO TREVENA

157. As a result of the foregoing wrongful conduct, Trevena and the Individual Defendants pursued the Phase 3 studies of oliceridine despite knowledge of the FDA's concerns and made or allowed to be made improper statements in the Company's press releases, public filings, and other public statements relating to, *inter alia*, the Company's Phase 3 studies for oliceridine. This misconduct has damaged Trevena's credibility and caused the Company to lose more than $150 million in market capitalization.

158. The Individual Defendants' improper course of conduct has also subjected the Company to potentially millions of dollars in damages in connection with the Securities Class Action. The Securities Class Action alleges that the Company, Gowen, and Soergel violated federal securities laws by repeatedly misrepresenting and failing to disclose material facts about the Company's interactions with the FDA concerning its leading drug candidate, oliceridine.

159. As a direct and proximate result of the Individual Defendants' conduct, the Company has expended, and will continue to expend, significant sums of money. These additional expenditures include, without limitation: (i) costs necessary to issue the appropriate corrective disclosures; (ii) compensation and benefits paid to the Individual Defendants and other members of Trevena's management, which compensation was based at least in part the Company's artificially-inflated stock price; (iii) compensation improperly paid to Trevena's named executive officers pursuant to the Company's cash-based Incentive Compensation Plan (ICP) for purportedly meeting objectives in 2016 and 2017 related to the progress of oliceridine's Phase 3 studies and, later, the submission of an NDA for the drug; (iv) costs of the additional studies (and related development costs) necessary due to Trevena's failure to timely alter its Phase 3 studies of oliceridine to address the FDA's concerns; and (v) costs incurred in investigating and defending Trevena and the Securities Class Action Defendants in the Securities Class Action and any related litigation.

160. The Individual Defendants' actions have further irreparably damaged Trevena's corporate image and goodwill. For at least the foreseeable future, Trevena will suffer from what is known as the "liar's discount," a term applied to the stock of companies who have been implicated in misleading the investing public, such that Trevena's ability to raise equity capital

or debt on favorable terms in the future is now and will continue to be impaired. The Company stands to incur higher marginal costs of capital and debt because of the misconduct.

IX. DERIVATIVE ALLEGATIONS

161. Plaintiff brings this action derivatively in her own right and for the benefit of the Company to redress injuries suffered, and to be suffered, by Trevena as a direct result of the violations of the federal securities laws, breaches of fiduciary duty, waste of corporate assets, and unjust enrichment by the Individual Defendants.

162. Trevena is named as a Nominal Defendant in this case solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

163. Plaintiff is a current shareholder of Trevena and has continuously owned such shares as described above at ¶ 21. Plaintiff will hold Trevena shares continuously throughout the pendency of this action and will adequately and fairly represent the interests of the Company and its shareholders in prosecuting this action.

164. Due to the Board's direct involvement in the wrongdoing, the substantial likelihood of liability its members face, and its members' lack of independence, prosecution of this action, independent of the current Board, is in the best interests of the Company and its shareholders.

165. The wrongful acts complained of herein subjected, and continue to subject, Trevena to harm.

X. DEMAND FUTILITY ALLEGATIONS

166. Plaintiff incorporates by reference all prior paragraphs as if fully set forth herein.

167. Trevena's current Board consists of non-party Scott Braunstein and defendants Gowen, Moulder, Dougherty, McHugh, Nunn, Phillips, Yanni, and Bourdow (the "Demand

Board"). A majority of these individuals are not disinterested and not independent with respect to the acts and omissions alleged herein. Plaintiff has not made any demand on the Demand Board to institute this action because such a demand would be a futile and useless act.

A. Demand Is Excused as to Defendants Gowen and Bourdow Because They Lack Independence

168. The Director Defendants concede in the Company's SEC filings that defendants Gowen and Bourdow are not independent directors. In its 2019 Proxy Statement, the Company admits that defendants Gowen and Bourdow are not "independent" under NASDAQ listing standards and SEC rules.

169. Trevena's Corporate Governance Guidelines further state that: "Only independent directors may serve on the Compensation Committee, Audit Committee, and Nominating and Corporate Governance Committee." Of the nine members of the Demand Board, only Gowen and Bourdow are not members of any of these committees.

170. Furthermore, defendant Gowen is not an independent director due to her history as the founder and an executive with Trevena. Gowen served as Trevena's President and CEO from 2007 until October 2018. In these positions, Gowen has received and continues to receive substantial monetary compensation and other benefits. Defendant Gowen also continues to be a substantial shareholder in Trevena, beneficially owning 2,181,564 shares of common stock (2.3% of outstanding shares) with a value exceeding $2 million.

171. Similarly, defendant Bourdow is not an independent director due to her current positions as Trevena's President, CEO, and Board member. Previously, she was the Company's SVP, Chief Commercial Officer and Executive Vice President and Chief Operating Officer. In her current and past executive positions and via her Board membership, Bourdow has received and continues to receive substantial monetary compensation and other benefits. Defendant

Bourdow also continues to be a substantial shareholder in Trevena, beneficially owning 477,625 shares of common stock with a value exceeding $450,000.

172. Defendant Gowen's and Bourdow's lack of independence renders them incapable of impartially considering a demand to commence and vigorously prosecute this action.

B. Demand Is Excused Because Most of the Demand Board Faces a Substantial Likelihood of Liability for Their Misconduct

173. Defendants Gowen, Moulder, Dougherty, McHugh, Nunn, Phillips, and Yanni breached their fiduciary duties of loyalty and good faith by making or allowing to be made improper statements in Trevena's press releases, public filings, and other public statements. Further, these defendants breached their fiduciary duties of loyalty and good faith by allowing the Company to go forward with its Phase 3 studies of oliceridine without first addressing the FDA's clear and explicit concerns. These defendants also failed to make a good faith effort to put in place a reasonable oversight system of these critical matters, and to the extent that a system was in place, they failed to appropriately monitor it. In making or allowing this improper conduct, defendants Gowen, Moulder, Dougherty, McHugh, Nunn, Phillips, and Yanni breached their fiduciary duties. Accordingly, these seven members of the Board face a substantial likelihood of liability for their breach of fiduciary duties, making any demand upon them futile.

174. Defendants Moulder, Phillips, and Yanni, as members of the Board's Compensation Committee, had additional duties with respect to monitoring the Company's progress towards key corporate goals and objectives (upon which executive compensation was partially based) including the progress of Phase 3 studies of oliceridine and the Company's interactions with the FDA related thereto. The Compensation Committee Defendants breached their fiduciary duty of loyalty as described above. For these reasons, defendants Moulder,

Phillips, and Yanni face a substantial likelihood of liability for their breach of fiduciary duties, making any demand upon them futile.

175. Defendants Dougherty and Yanni, as members of the Audit Committee, had a duty to properly review and approve all press releases containing information relating to material developments. They further had a duty to assist the Board in ensuring the adequacy and effectiveness of internal controls including financial and disclosure controls and procedures, and overseeing compliance with material legal and regulatory requirements. Thus, the Audit Committee Defendants breached their fiduciary duty of loyalty and good faith by approving and otherwise allowing the improper statements, failing to properly oversee Trevena's disclosure controls and procedures, and failing to ensure compliance with material legal and regulatory requirements. For these reasons, defendants Dougherty and Yanni face a substantial likelihood of liability for their breach of fiduciary duties, making any demand upon them futile.

176. Any suit by the current directors of Trevena to remedy these wrongs would also expose defendants Gowen, Soergel, and Trevena to liability for breach of fiduciary duties and violations of the federal securities laws in the pending Securities Class Action and could result in civil actions being filed against one or more of the other Individual Defendants. If the Board elects for the Company to press forward with its right of action against defendants Gowen, Soergel, and others in this action, then the Company's efforts would compromise its own defense of the Securities Class Action.

C. Demand Is Excused as to Non-Defendant Braunstein and Defendant Nunn Due to Their Ongoing Business Activities

177. Non-defendant Braunstein has served as the Operating Partner of Aisling since 2015. Aisling is an investment firm that invests in products, technologies and global

businesses in the healthcare space. Since 2000, Aisling has raised over $1.8 billion across four of its funds.

178. Defendant Nunn has been a Partner and Venture Advisor at New Enterprise Associates, Inc. (NEA) since 2006. NEA claims to be one of the world's largest and most active venture capital firms. NEA also invests in healthcare.

179. Both Aisling and NEA operate in an extremely competitive venture capital market dominated by company founders and long-term employees such as defendant Gowen. If these directors were to pursue litigation against a company founder, such as Gowen, they would risk ruining their reputations in the venture capital market and would risk losing lucrative future opportunities for themselves and their companies to invest in other developmental stage entities.

180. In fact, Aisling and NEA frequently work together to fund various healthcare-related ventures. By way of example, they both invested in Loxo Oncology, Inc., Advanced Cardiac Therapeutics, Inc., Earlens Corporation, Inc., Dermira, Inc., TapImmune Inc., and Verona Pharma plc. Thus, Braunstein would be even more reluctant to jeopardize future deals with NEA by taking a position that is potentially adverse to the interests of Nunn (and NEA), who faces liability for his actions with respect to Trevena. For these reasons, it is impossible for each of them to independently and disinterestedly consider a shareholder demand to investigate or prosecute an action pertaining to Gowen's and/or the other Individual Defendants' illegal conduct.

D. Demand Is Excused as to Defendants Moulder, Phillips and Yanni Due to Their Membership on the Compensation Committee

181. Defendants Moulder, Phillips and Yanni serve together on the Compensation Committee. These three individuals set at least portions of their own compensation, as well as the compensation of their colleagues, Gowen, Dougherty, McHugh, Nunn, and Bourdow. Their

capacity to dole out compensation for themselves and their colleagues, including judging whether and to what extent certain corporate objectives have been met in connection with incentive compensation, makes it impossible for each of them to independently and disinterestedly consider a shareholder demand to investigate or prosecute an action pertaining to the Individual Defendants' illegal conduct.

XI. CLAIMS FOR RELIEF

COUNT I

For Contribution for Violations of §10(b) and §21D of the Exchange Act (Against Gowen and Soergel)

182. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

183. Defendants Gowen and Soergel are named defendants in the Securities Class Action.

184. Trevena is named as a defendant in the Securities Class Action, which asserts claims under the federal securities laws for, *inter alia*, violations of § 10(b) of the Exchange Act. If the Company is found liable for violating the federal securities laws, the Company's liability will arise, in whole or in part, from the intentional, knowing, or reckless acts or omissions of some or all of the defendants as alleged herein. The Company is entitled to receive contribution from those defendants in connection with the Securities Class Action against the Company.

185. Defendants Gowen and Soergel as directors and officers and otherwise, had the power and/or ability to, and did, directly or indirectly, control or influence the Company's general affairs, including the content of public statements about Trevena, and had the power and/or ability, directly or indirectly, to control or influence the specific corporate statements and conduct that violated § 10(b) of the Exchange Act and Rule 10b-5. Further, defendants Gowen

and Soergel are liable under § 21D of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of any private right of action for contribution asserted pursuant to the Exchange Act.

186. As a result, defendants Gowen and Soergel damaged Trevena and are liable to the Company for contribution.

187. Plaintiff, on behalf of Trevena, has no adequate remedy at law.

COUNT II

Breach of Fiduciary Duties
(Against the Individual Defendants)

188. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

189. The Individual Defendants owed and owe Trevena fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe Trevena the highest obligation of good faith, fair dealing, loyalty, and due care.

190. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as officers and directors of Trevena, the absence of good faith on their part, and a reckless disregard for their duties to the Company that the Individual Defendants were aware, or reckless in not being aware, posed a risk of serious injury to the Company.

191. The Individual Defendants breached their duty of loyalty and good faith by: (i) allowing the Company to press forward with its Phase 3 studies knowing that the FDA did not agree with, among other things, Trevena's proposed dosing, its proposed primary endpoint, and its proposed noninferiority margin; (ii) allowing each other to cause, or by themselves causing, the Company to make improper statements in Trevena's press releases, public filings, and other public statements relating to oliceridine and the Company's key interactions with the FDA,

including the March 29, 2016 End-of-Phase 2 meeting; and (iii) failing to properly maintain and/or adequately monitor internal controls which would have prevented the foregoing violations of law. These unlawful practices wasted the Company's assets and caused Trevena to incur substantial damage.

192. The Securities Class Action Defendants were reckless or grossly negligent in disseminating the improper statements detailed herein. The Securities Class Action Defendants intentionally, recklessly, or with gross negligence made improper statements in Trevena's press releases, public filings, and other public statements. Accordingly, these defendants breached their duty of care and loyalty to the Company. These unlawful practices wasted the Company's assets and caused Trevena to incur substantial damage.

193. The Board members had a duty to properly oversee compliance with Trevena's Code of Conduct. The Code of Conduct, which applies to all directors, officers, and employees, requires "a high degree of transparency relative to the research," full, fair, accurate, timely and understandable disclosure in the Company's public statements, and that Company communications satisfy all applicable regulatory and legal requirements. As described herein, the Individual Defendants breached their duty of loyalty and good faith by failing to properly oversee compliance with the Code of Conduct by, *inter alia*, making or allowing to be made the improper statements described herein.

194. The Compensation Committee members, and the Board as a whole, had a duty to actively and appropriately oversee, monitor and confirm the Company's progress towards critical corporate goals and award incentive compensation to Trevena's executive officers based upon actual progress toward these predetermined objectives. As described herein, these defendants breached their duty of loyalty and good faith by failing to properly monitor the Company's

progress towards critical corporate goals (including those related to advancing studies and FDA approval of oliceridine) and/or by failing to award incentive compensation based thereon.

195. The Audit Committee members had a duty to review and approve all press releases containing information relating to material developments regarding the Company prior to dissemination including those alleged to be false and misleading herein. They also had a duty to properly oversee the adequacy and effectiveness of the Company's internal controls including financial and disclosure controls and procedures, the Company's legal, regulatory, and ethical compliance, and the Company's enterprise risk management. As described herein, the Audit Committee Defendants breached their fiduciary duty of loyalty and good faith by approving and otherwise allowing the improper statements, failing to properly oversee Trevena's disclosure controls and procedures, and failing to ensure compliance with material legal and regulatory requirements.

196. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Trevena has sustained significant damages. Accordingly, these defendants are liable to the Company.

197. Plaintiff, on behalf of Trevena, has no adequate remedy at law.

COUNT III

Waste of Corporate Assets
(Against the Individual Defendants)

198. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

199. As a result of the Individual Defendants' failure to implement adequate controls and monitor them to ensure that the Company's SEC filings and other public statements were not misleading, Trevena is subject to the Securities Class Action. The Individual Defendants have

caused Trevena to waste its corporate assets by forcing the Company to expend valuable resources in defending itself in the ongoing litigation, in addition to any ensuing costs from a potential settlement or adverse judgment.

200. As a result of the Individual Defendants' failure to implement adequate controls and monitor them to ensure that the Company's Phase 3 studies were acceptable to the FDA, Trevena must now expend additional valuable resources in continuing to pursue FDA approval of oliceridine.

201. As a result of their waste of corporate assets, the Individual Defendants are liable to the Company.

202. Plaintiff, on behalf of Trevena, has no adequate remedy at law.

COUNT IV

Unjust Enrichment
(Against the Individual Defendants)

203. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

204. By their wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of and to the detriment of Trevena. The Individual Defendants were unjustly enriched as a result of the compensation and director remuneration they received while breaching fiduciary duties owed to Trevena.

205. Plaintiff, as a shareholder and representative of Trevena, seeks restitution from these defendants, and each of them, and seek an order of this Court disgorging all profits, benefits, and other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

206. Plaintiff, on behalf of Trevena, has no adequate remedy at law.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Finding that a shareholder demand on the Trevena Board would have been a futile and useless act;

B. Finding that the Individual Defendants have breached their fiduciary duties to the Company, wasted corporate assets, were unjustly enriched, and violated the federal securities laws;

C. Directing Trevena to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Trevena and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for amendments to the Company's Bylaws or Articles of Incorporation, and taking such other action as may be necessary to place before shareholders for a vote the following corporate governance proposals or policies:

- a proposal to strengthen the Company's disclosure controls to ensure that all material information is adequately and timely disclosed to the SEC and public;
- a proposal to strengthen the Board's supervision of operations and compliance with applicable laws and regulations;
- a proposal to strengthen the Company's internal reporting controls;
- a proposal to declassify the Board;
- a proposal to develop and implement procedures for greater shareholder input into the policies and guidelines of the Board;
- a provision to permit the shareholders of Trevena to nominate three candidates for election to the Board; and
- a provision to appropriately test, and then strengthen, the Company's internal-operational control functions;

D. Against each of the Individual Defendants in favor of Trevena for the amount of damages sustained by Trevena, jointly and severally, in an amount to be determined at trial, together with pre- and post-judgment interest at the maximum legal rate allowable by law;

E. Requiring the Individual Defendants to return to Trevena all compensation and remuneration of whatever kind paid to them by Trevena during the time that they were in breach of the fiduciary duties they owed to Trevena;

F. Directing the Individual Defendants to establish, maintain, and fully fund effective corporate governance and compliance programs to ensure that Trevena's directors, officers, and employees do not engage in wrongful or illegal practices;

G. Granting additional appropriate equitable and/or injunctive relief to remedy the Individual Defendants' misconduct, as permitted by law;

H. Awarding to Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees and expenses; and

I. Granting such other and further relief as this Court deems just and equitable.

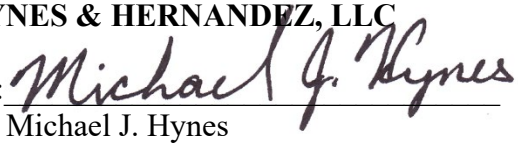
XIII. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Dated: November 12, 2019

Respectfully submitted,

HYNES & HERNANDEZ, LLC

By: 

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Attorneys for Plaintiff

VERIFICATION

I, Lisa McKernan, verify that I have reviewed the foregoing Verified Shareholder Derivative Complaint for Violations of Federal Securities Laws, Breach of Fiduciary Duty, Waste of Corporate Assets, and Unjust Enrichment, and that the allegations as to me are true and correct and that the other allegations upon information and belief are true and correct.

Dated: November 4, 2019

DocuSigned by:
A6B5E581277A24EF...

Lisa McKernan

JS 44 (Rev 02/19) CMR **CIVIL COVER SHEET** 19-cv-5314

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

19 5314

I. (a) PLAINTIFFS

Lisa McKernan, Derivatively on Behalf of Trevena, Inc

(b) County of Residence of First Listed Plaintiff Montgomery County, PA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Michael J. Hynes
Hynes & Hernandez, LLC
101 Lindenwood Drive, Suite 225, Malvern, PA 19355 (484) 875-3116

DEFENDANTS

Maxine Gowen, David Soergel, Carrie L. Bourdow, Leon O. Moulder, Jr., Michael R. Dougherty, Julie H. McHugh, Jake R. Nunn, Anne M. Phillips, Barbara Yanni, Adam M. Koppel, and Nominal Defendant Trevena, Inc.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for Nature of Suit Code Descriptions

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☒ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*
§ 21D of the Exchange Act, 15 U.S.C. § 78u-4(f)

Brief description of cause
Breach of Fiduciary Duties, Waste of Corporate Assets, Unjust Enrichment, and Violations of Sections 10(b) and §21D of the Securities Exchange Act of 1934

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*

JUDGE Honorable Cynthia M. Rufe DOCKET NUMBER 2:18-cv-5482

DATE 11/12/2019

SIGNATURE OF ATTORNEY OF RECORD Michael J. Hynes

NOV 12 2019

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

CMR

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

19 5314

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 1700 Fort Washington Ave., Maple Glen, PA 19002

Address of Defendant: 955 Chesterbrook Boulevard, Suite 110 Chesterbrook, PA 19087

Place of Accident, Incident or Transaction Chesterbrook, Pennsylvania

RELATED CASE, IF ANY:

Case Number: 2:18-cv-5482 Judge Honorable Cynthia M. Rufe Date Terminated

Civil cases are deemed related when *Yes* is answered to any of the following questions

1	Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?	Yes ☐	No ☑
2	Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?	Yes ☑	No ☐
3	Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court?	Yes ☐	No ☑
4	Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?	Yes ☐	No ☑

I certify that, to my knowledge, the within case ☑ **is** / ☐ **is not** related to any case now pending or within one year previously terminated action in this court except as noted above

DATE 11/12/2019 Michael J. Hynes 62702

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

CIVIL: (Place a √ in one category only)

A. Federal Question Cases:

- ☐ 1 Indemnity Contract, Marine Contract, and All Oth
- ☐ 2 FELA
- ☐ 3 Jones Act-Personal Injury
- ☐ 4 Antitrust
- ☐ 5. Patent
- ☐ 6 Labor-Management Relations
- ☐ 7 Civil Rights
- ☐ 8 Habeas Corpus
- ☐ 9 Securities Act(s) Cases
- ☐ 10 Social Security Review Cases
- ☑ 11 All other Federal Question Cases

(Please specify) Stockholders' Suits

THIS CASE IS RELATED TO: 18cv5482

CIVIL ACTION NO. 19 5314
CRIMINAL NO.

ASSIGNED TO: Judge Rufe

(The effect of this

I, Michael J. Hynes, counsel of record *or* pro se plaintiff, do hereby certify

☑ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs

☐ Relief other than monetary damages is sought

DATE 11/12/2019 Michael J. Hynes NOV 12 2019 62702

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38

Civ. 609 (5/2018)

CMR

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Lisa McKernan, Derivatively on Behalf of Trevena, Inc. : CIVIL ACTION

v. :

Maxine Gowen, David Soergel, Carrie L. Bourdow, Leon O Moulder, Jr., Michael R Dougherty, Julie H. McHugh, Jake R. Nunn, Anne M. Phillips, Barbara Yanni, Adam M Koppel, and Nominal Defendant Trevena, Inc : NO. 19 5314

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management - Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

11/12/2019	Michael J. Hynes	Plaintiff
Date	**Attorney-at-law**	**Attorney for**
(484) 875-3116	(914) 752-3041	mhynes@hh-lawfirm.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

NOV 12 2019